Medical and Health Research Ethics Committee (MHREC)

Submission Criteria and Review Process Guidelines

Ministry of Health

Brunei Darussalam

June 2024

Medical and Health Research Ethics Committee (MHREC) Submission Criteria and Review Process Guidelines 2024

Table of contents:

1. Introduction

1.1 This document aims to provide a guideline on which activities/ studies require submission to MHREC for approval. The need to decide if an activity requires ethical review is a fundamental part of good research practice.

2. Definitions

2.1 Research:

a. Is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalisable knowledge" (Source: US Code of Federal Regulation Title 45 Part 46). It aims to generate new insights, theories or applications that advance the understanding of a particular subject area.

2.2 Human subject research:

a. Is research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private

information is used/studied/analyzed/generated. (Source: US Code of Federal Regulation Title 45 Part 46).

2.3 Case reports:

a. Present detailed descriptions of individual cases, often focusing on rare or unusual medical conditions, treatments, or outcomes. They are typically not considered formal research unless they involve multiple cases (case series), systematic data collection, analysis, and contribute to generalisable knowledge beyond individual patient management.

2.4 Audits:

a. Involve the systematic review and evaluation of healthcare practices, processes, or outcomes against established standards or guidelines.
b. They are generally considered quality improvement activities rather than formal research, as they focus on assessing and improving the quality and efficiency of healthcare delivery **within a specific setting**.
c. However, audits may evolve into research if they involve systematic data collection, analysis, and dissemination of findings aimed at generating generalisable knowledge or informing broader healthcare practices **beyond the audited setting.**

3. Which activities/studies do not require submission to MHREC?

3.1 Non-human subject research.

3.2 Public health activities including public health surveillance, as part of the Infectious Disease Act, cap. 204.

3.3 Clinical audit, quality improvement projects and program evaluation conducted with the **sole purpose** of improving the quality of patient care within that institution, or to assess the effectiveness or impact of healthcare programs or interventions. Provided that:

a. There is no intention to generate generalisable knowledge. The activities are conducted for internal improvement purposes and do not involve external research or publication.
b. Subjects are under the medical care of the researcher's team.
c. These activities do not pose any potential harm to participants.
d. However, audits may evolve into research if they involve systematic data collection, analysis, and dissemination of findings aimed at generating generalisable knowledge or informing broader healthcare practices beyond the audited setting. **In this case, MHREC approval is needed.**

3.4 Case reports or case series of three or less patients with no patient identifier included in the report.
   a. All case reports require written consent from the patient or legal guardian.

3.5 Literature review and activities that use only information that is already available in the published reports in the public domain, such as published in scientific journals or posted on governmental or institutional websites.

4. Which activities do require submission to MHREC?

4.1 All health research activities that involve human participants. See definition for research.

5. MHREC review processes

5.1 All submissions to MHREC will be allocated to either:
   a. Full Review, or
   b. Expedited Review

5.2 Review process will be determined by MHREC after reviewing the submission.

6. Full Review

6.1 All research proposals that are not eligible for expedited review will undergo full review.

6.2 This involves presentation by the primary researcher and clinical supervisor to the MHREC members during MHREC meeting.

7. Expedited Review

7.1 The expedited review process is intended to facilitate efficient evaluation of low-risk research projects while upholding ethical standards and protecting the rights and welfare of research subjects.

7.2 Safety and confidentiality of data collected must be ensured.

7.3 This involves streamlined evaluation of the research proposal, informed consent documents, and any data management plans.

7.4 Research proposals **may be eligible** for expedited review if they meet the following criteria:

a. Research with no more than minimal risk posed to the participants e.g., research with no interventions to standard of care.
b. Research that involves non-invasive methodologies or procedures, such as surveys or interviews.
c. Multi-centre studies that have already been approved by another ethics committee or institutional review board.
d. Research involving materials (data, documents, records, or specimens) that have been collected solely for non-research purposes, such as medical treatment or diagnosis.
e. Research that is time-sensitive or has a significant public health benefit.
f. Research with no direct patient contact e.g., involving clinical notes only.

8. References

8.1 WHO ERC Submission and Exemption advise v2.docx 15.03.2023

8.2 Ethics Guidelines for Human Biomedical Research by the Bioethics Advisory Committee (BAC), Singapore 2015

8.3 Medical Research Ethics Committee (MREC) & National Committee for Clinical Research, Malaysia