TYPES OF REVIEW

There shall be five (types) of review, namely;

1. Expedited review.
2. Full review
3. Exempt review
4. Continuing review
5. Review of Amendments to a previously approved Proposal

Expedited Review

Expedited review refers to the review of a limited class of research outside of a convened IRB meeting.

i) MNTRH – IREC Secretary/Deputy Secretary/ Human Participant Administrator shall carry out an administrative review to determine if the research falls in the expedited category.
ii) Expedited review will be carried out by a designated member of the MNTRH–IREC or a designated expert other than a committee member.
iii) Once a reviewer determines that an application does not qualify for an expedited review, they shall notify the administrator or secretary who will table in the next meeting.
iv) If the reviewer determines that the criteria for approval has been met, they may recommend approval pending ratification by the committee in the next meeting.
v) Expedited approval shall be recommended by the Secretary in consultation with the Chairperson but pending ratification by the Committee.

The following categories of research proposals may qualify for an expedited review and approval:

a) Research investigation that presents no more than minimal risk to the study participants at initial review or continuing review.
b) Minor amendments in previously approved research during the period in which approval was granted.

Definitions of "minimal risk" and "minor amendment" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life.

FULL REVIEW

All other research proposals submitted for review which do not meet the criteria for expedited and exempt review shall undergo a full review process. These proposals have more than minimal risk to participants and involve contact with vulnerable populations, may involve data that could be traced or linked to individual participants' and could also involve direct interventions to participants that may have physical or psychological harm.

EXEMPT REVIEW

i) Research protocols that are exempt from review are those that do not require formal approval from the full ethical committee prior to their conduct. These are studies where there is 'minimal risk'.

ii) Minimal risk ids defined by the federal regulations as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in thr routine medical, dental or psychological examination of healthy persons.

iii) Research studies involving vulnerable groups do not qualify to be exempt from review, its conduct must still be in line with all relevant national and institutional standards of ethics and codes of professional conduct unless otherwise defined by the Committee and other regulations.

iv) To qualify for review at the exempt level, the research must not be greater than minimal risk and must fall into one or more of the exempt categories described below.

   a. Education **research**
   b. Surveys, interviews, educational tests, public observations (that do not involve children)
   c. Benign behavioural interventions
   d. Analysis of previously-collected, unidentified info/specimens
   e. National **research**/demonstration projects
   f. Taste and food evaluation **studies**

v) The Secretary, Deputy Secretary or Human Participant Administrator will carry out administrative review to determine whether the protocols will be categorised under this or any other review category.

vi) Exempt review will be conducted by at least one reviewer.

vii) Exempt approvals could be given by the Secretary in consultation with the Chairperson but pending ratification by the Committee.

i) The Reviewer or Committee may recommend the proposed research to be re-categorised to undergo full review.

CONTINUING REVIEW

i) All studies approved by MNTRH-IREC will require to seek continuing review upon expiry of their approval if they intend to continue study related activities beyond the one-year approval.

ii) A comprehensive progress report shall be required upon request for study continuation together with a duly filled MNTRH-IREC continuing review form.

iii) All studies that have completed study related activities shall be required to provide a final study report and a duly filed MNTRH-IREC study close out form.

iv) Continuing review submissions must include all current MNTRH-IREC approved study documents, even if they have not changed since the last review.

v) MNTRH-IREC may withdraw approval of a protocol previously approved.

vi) The responsibility for the application for Continuing Approval lies with the researcher.

vii) The Principal Investigator should submit the application at least **60 calendar days** before expiry of the approval period. No study should continue without seeking re-approval.

viii) All continuing review applications shall be reviewed by the Monitoring and Evaluation Sub-Committee and the decisions of the Sub-Committee ratified at the full board meeting.

ix) The review will occur annually, unless the level of risk requires more frequent reviews, in which case the Principal Investigator shall be so advised.

x) The decision could be as follows;

   a) Continue as originally approved.
   b) Have some modifications
   c) Request a site visit by the safety monitoring committee
   d) Be suspended
   e) Be terminated

xi) The Secretariat shall inform the Principal Investigator the outcome of the application and reasons for the decision. All conditions set by the Committee shall be met before consideration for re-approval.

The application for review of continuation of study should include the following information and materials that should be availed in e-copies only;

a) Continuing Review form, accompanied by a progress report.
b) Consent/assent forms
c) Recruitment materials
d) Data collection instruments (surveys, interview questions, stimuli, etc.)
e) Other forms of documents utilised with human participants
f) DSMB Report (if applicable) please refer to the reviewer guideline form
g) Research personnel list for Continuing Review
h) If there is failure to seek Continuing Approval the study will be terminated.

REVIEW OF STUDY AMENDMENTS

Amendments are defined as any changes to an approved research protocol. All amendments to the study proposal shall be communicated to MNTRH-IREC.

i) Minor amendments do not change the risk benefit profile of the study including change of title, administrative changes, adding an investigator, changes that do not affect study design

and outcomes, small changes to letters of information and consent such as editorial changes.

ii) Major amendments do change the risk benefit profile of the study e.g. change in study aims and objectives, alterations to study procedure, changing inclusion criteria, substantive changes to the letter of information and consent.

The application for review of amendment should include the following information and materials, which should be availed in e-copies only.

a. Cover letter detailing the amendments.
b. Amendment form with clear justification for the major amendments
c. Newly developed documents that support the proposed research modification
d. Proof of payment receipt for the requested modification