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|---|---|---|
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| **DISEMAK OLEH:** | **MEDICAL RESEARCH ETHICS COMMITTEE** | |
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| **DISAHKAN OLEH WAKIL PENGURUSAN:** | **KOSONGKAN** | |

## TABLE OF CONTENTS


| No. | ITEM | PAGE |
|---|---|---|
| 1 | TABLE OF CONTENTS | 2 |
| 2 | ABBREVIATIONS | 3 |
| 3 | INTRODUCTION, OBJECTIVES AND SCOPE | 4 |
| 4 | RESPONSIBILITIES | 5 |
| 5 | ELIGIBILITY AND APPLICATION PLATFORM | 6-7 |
| 6 | APPLICATION SUBMISSION | 7-9 |
| 7 | INITIAL REVIEW WORKFLOW | 10-11 |
| 8 | PROTOCOL REVIEW | 11-12 |
| 9 | MREC MEETING WORKFLOW | 12-20 |
| 10 | SPECIAL MEETING WORKFLOW | 20-21 |
| 11 | APPENDIX 1: REVIEW ASSESSMENT FORM | 22-27 |
| 12 | APPENDIX 2: SUMMARY OF MREC REVIEW AND DECISION | 28 |

## ABBREVIATIONS

| ABBREVIATION | FULL TEXT |
|---|---|
| GCP | Good Clinical Practice |
| IEC | Independent Ethics Committee |
| IRB | Institutional Review Board |
| MREC | Medical Research Ethics Committee |
| PI | Principal Investigator |
| UMMC | University of Malaya Medical Centre |
| RAF | Review Assessment Form |
| SAE | Serious Adverse Events |

## 1.0 INTRODUCTION

The Medical Research Ethics Committee of the University of Malaya Medical Centre is responsible for reviewing and providing ethical approval for research involving human subject conducted in University of Malaya Medical Centre. The MREC reviews study documents and makes decisions on approval in compliance with the Malaysian Guideline for Good Clinical Practice and policies of UM and UMMC.

## 2.0 OBJECTIVES

This SOP describes studies that are eligible for MREC review and decision; platform for submission of applications; the criteria of review and decision; the review process including expedited review as well as full board review; and workflow for special review meetings.

## 3.0 SCOPE

3.1 The UMMC-MREC reviews protocols and other study documents of research which are conducted in the Faculty of Medicine, University of Malaya (FOM-UM) and UMMC. These include studies by:

- FOM-UM staff and students,
- UMMC staff and students,
- UM staff and students who are not from FOM-UM, and
- Non-UM/UMMC investigators.

3.2 This SOP applies to the actions by the UMMC-MREC from the submission of new study application to the decision on an application. This SOP also describes the full board meeting which may also involve discussion on post approval matters.

## 4.0 RESPONSIBILITIES

4.1 The UMMC-MREC uses an online application submission system. It is the responsibility of the Secretariat Staff to communicate with the Information Technology personnel to resolve any issue in the system. The Secretariat Staff is also responsible to process and ensure study documents submitted are complete before forwarding it to the Chair or Deputy Chair for further instructions. The Secretariat Staff is also responsible for arranging for MREC meetings and to ensure that deliberations and discussions in MREC meetings are adequately documented.

4.2 The Chair and Deputy Chair are responsible to review all protocols submitted. They also decide whether a study protocol should be granted expedited approval or tabled for meeting. The committee members are responsible to review, evaluate and propose a decision for the protocols tabled for MREC meetings.

4.3 Each category of MREC members has the following specific tasks in the review of study documents:

- Medical/Scientific members shall review protocols, participant information sheets (PIS) and other supporting documents, to ensure that all medical and clinical aspects, scientific aspects including research design and methodologies, and ethics, are sound, acceptable and in compliance with MGCP.
- Laypersons shall review PIS to ensure the information is consistent with that in the protocol, is non-technical and easily understood by lay persons, language is age-appropriate (for assent) and is compliant with requirements of MGCP.

4.4 Principal Investigators (PIs) are responsible for submitting their complete set of study documents to the UMMC-MREC in their application. They or their co-investigators may be required to be present at the UMMC-MREC meetings to present their studies and to answer any queries.

## 5.0 ELIGIBILITY AND APPLICATION PLATFORM

### 5.1 **Eligible applicants**

- Investigators from UMMC or FOM, University of Malaya. Investigators who are not from UMMC/FOM must appoint a PI from UMMC/FOM who will submit the application.
- Students (post-graduate) from FOM. Each student must include the UMMC/FOM supervisor's name in the application.
- Students who are not from FOM or undergraduate students from FOM must appoint a staff from UMMC/FOM as a PI who will submit the application.
- Research assistant, study coordinator, clinical research officers or any personnel from industry are not eligible. The UMMC/FOM investigator who is on the study team should submit the application.

### 5.2 **Application Platform**

- All applications for new study are to be submitted online at:
  - *http://my.ummc.edu.my* – for UMMC/FOM staff who have Single Sign On (SSO) account login at (e-Service > iResearch)
  - *https://eservices.ummc.edu.my* - for UMMC staff/FOM staff/FOM student who do not have Single Sign On (SSO) login.
- Figure 1 summarises the eligibility of application as well as the application platform according to the category of applicants.

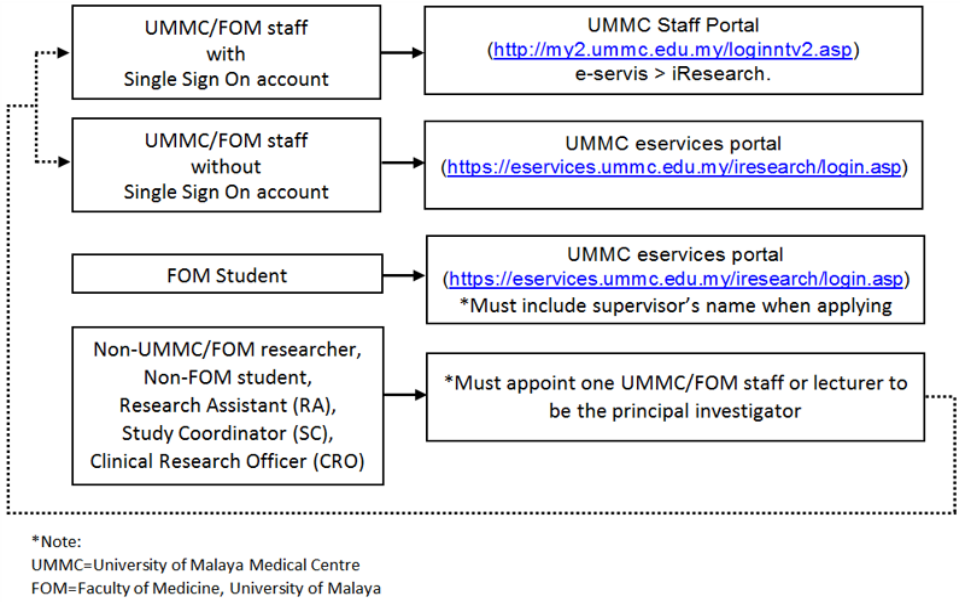



Figure 1. Application Eligibility and Platform

## 6.0 APPLICATION SUBMISSION

6.1 All applications must be submitted through the online application system as described in section 6.2. The system will automatically generate a study identification number (MREC ID) for each new application.

6.2 All items in the online application form must be answered and accompanied by the following documents. Wherever applicable, version number and version date must be provided for each document:

- Study protocol.
- Written participant information sheet and consent form in English or Bahasa Malaysia.
- Subject recruitment procedures / advertisements (if applicable)
- Questionnaires, data collection form, interview guide (if applicable)
- Investigator's Brochure (if applicable).
- Available safety information (if applicable).
- Information about payment and compensation available to subjects (if applicable).
- Brief current curriculum vitae of PI and all co-investigators.

- GCP certificates of PI and all co-investigators who deal in patient care (for clinical trials only).

6.3 Figure 2 shows the process of a new study application.

Figure 2: The process of new study applications.

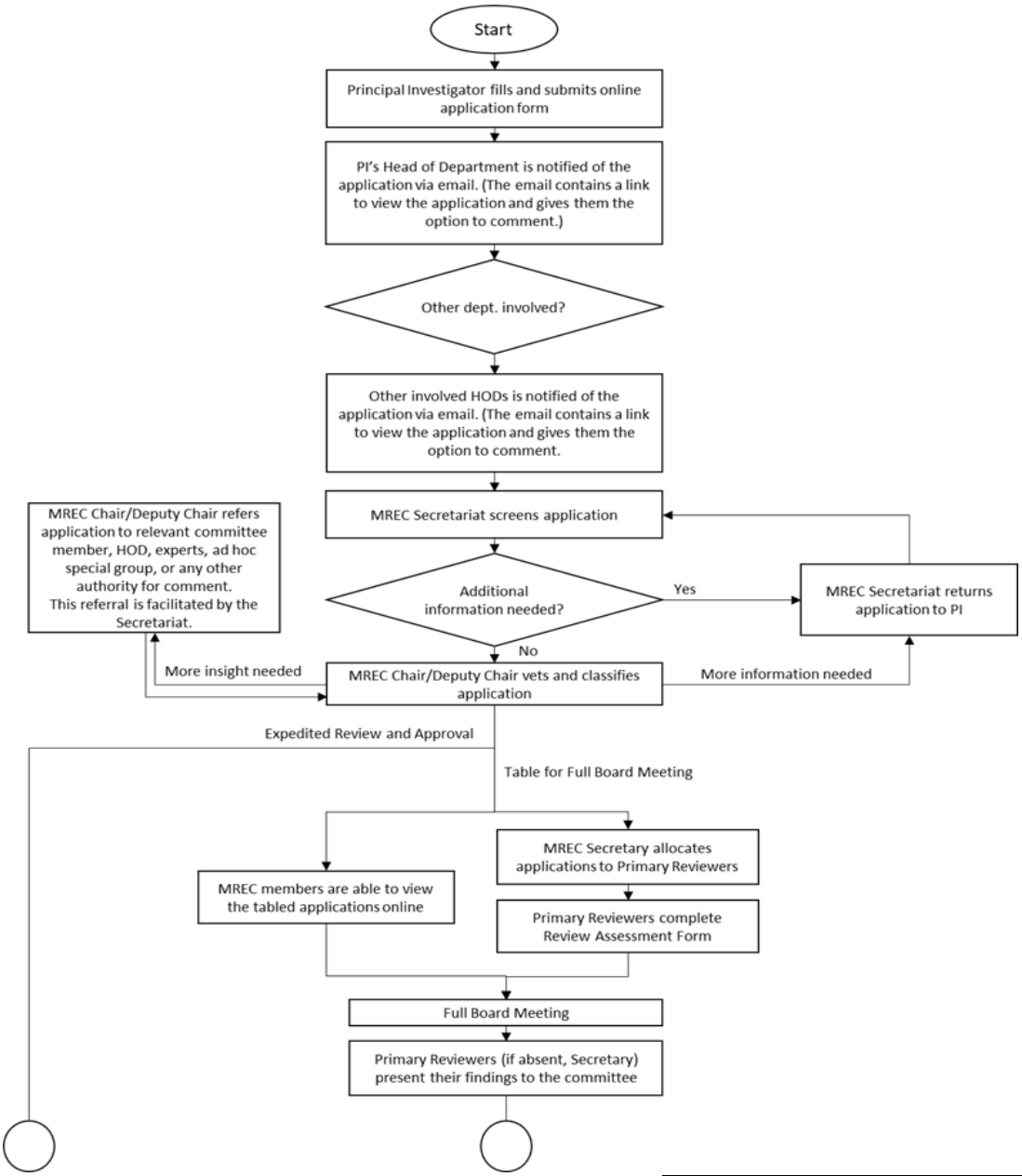
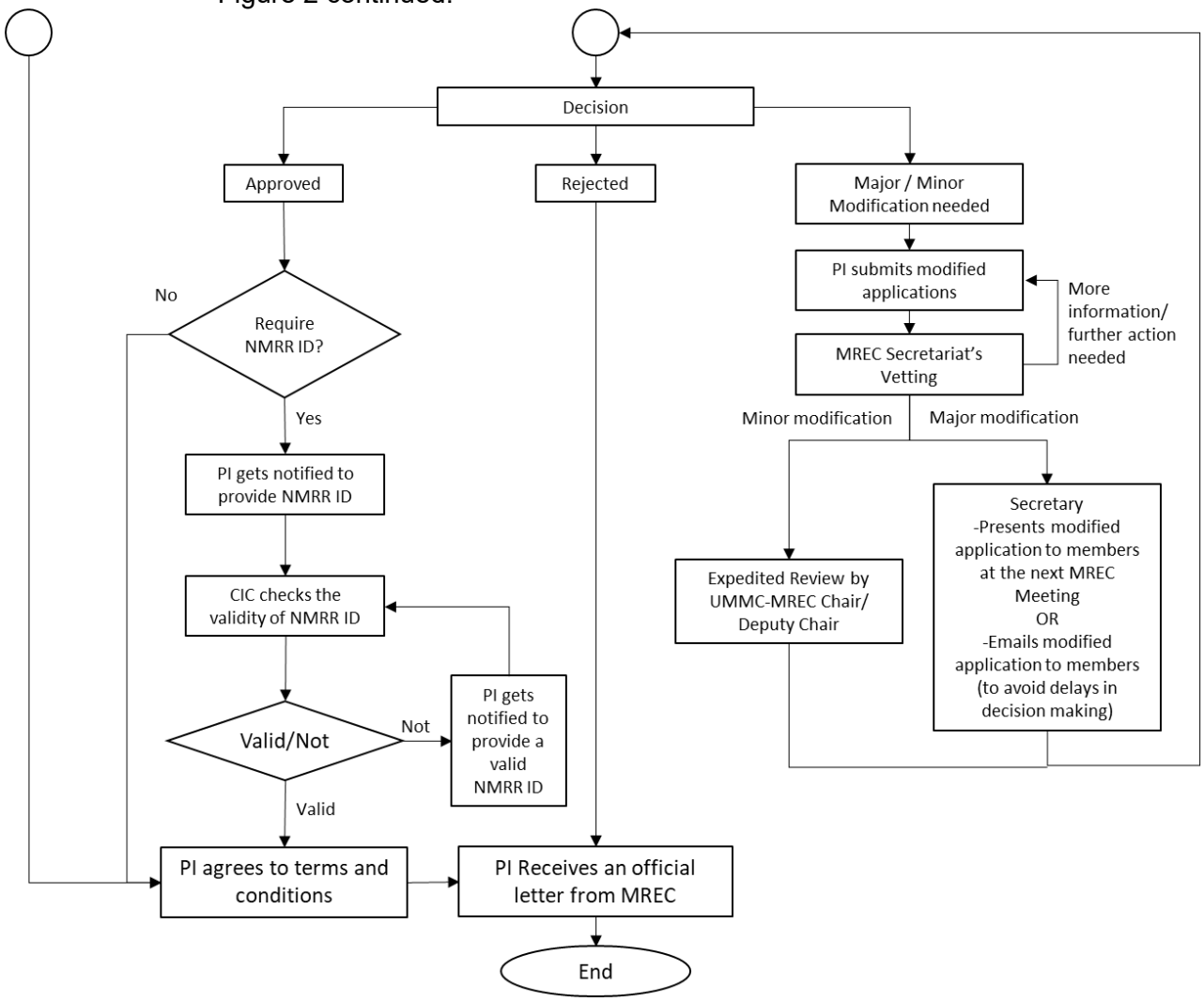


Figure 2 continued:



## 7.0 INITIAL REVIEW WORKFLOW

### 7.1 **Preliminary stage**

- Each online complete application shall be sent to the HOD of the applicant for comments. The system will notify the HOD by email. If there is no comment from the HOD after 3 working days, the application will proceed to the next stage.
- If the study involves other departments, the application shall be sent to the HODs of those departments for comments. If there is no comment from those HODs after 3 working days, the application will proceed to the next stage.
- The application is next sent to the MREC Secretariat to check for completeness according to the submission checklist (Appendix 3).

### 7.2 **Classification of review**

- The Secretary screens all new complete study applications.
- All applications will be forwarded to the Chair or Deputy Chair for classification.
- The Chair or Deputy Chair will decide, within 14 working days of receipt of an application, whether the proposed application or report shall be:
  - granted expedited review and approval
  - tabled for discussion at the MREC meeting
  - referred back to the applicant for clarification or revision (if information is incomplete or unclear)
  - referred to relevant committee member, HOD, relevant experts, relevant ad hoc special group or any other relevant authority for comment before further action is to be taken
- Expedited review and approval are considered for studies that pose no more than minimal risks to subjects e.g.:
  - no intervention or interference to current treatment
  - no invasive procedures
  - involve collection of small volume blood samples
  - involve only questionnaire survey, qualitative interview, case-notes, laboratory studies and secondary data analysis.

- Studies classified for expedited review will be reviewed by the Chair. The Chair should complete the expedited review within 14 working days of classification for expedited review. Decisions that the Chair can make are:
  a) Approve
  b) Further action required
  c) Re-classify for full board meeting
- Studies approved by expedited review will be tabled at the next MREC meeting for endorsement.
- Studies that do not qualify for expedited review, will be reviewed at a full board MREC meeting.
- Studies for full board review shall first undergo primary review by 2 MREC members (1 medical/scientific with expertise relevant to the study topic and 1 layperson) selected by the Chair. The primary reviewers shall complete the RAF and submit to the Secretary within 14 working days of being assigned. The completed RAF will be used to facilitate discussion at the MREC meeting.

## 8.0 PROTOCOL REVIEW

8.1 A Review Assessment Form (RAF) is used for all reviews including expedited and full board review.

8.2 Each protocol is evaluated in terms of (but not limited to):

- Competency of investigator - to consider the qualifications of the investigator as documented in current curriculum vitae and / or any other relevant documentation to determine whether the investigators have the necessary experience and skills to conduct the study.
- Purpose of study - to determine if the study objectives and outcomes are clear and well explained.
- Study justification - to find out whether the study has value, answers an important question, and whether similar studies have been done before.
- Scientific rigour - to evaluate whether the study design and methodologies are appropriate.
- Involvement of vulnerable population - to determine whether there are appropriate measures to ensure vulnerable subjects such as pregnant women, children, indigenous populations, sex workers,

prisoners, and marginalized as well as stigmatized groups, are not being disadvantaged.

- Benefits - to assess whether there are benefits to the subjects.
- Risks - to examine the risks to subjects and the actions taken to minimise those risks, especially for studies that involve the use of placebo, untested procedure (investigatory or therapeutic) as well as involving genes or stem cells.
- Confidentiality - to ensure that researchers keep study data confidential and participants' personal identifiable information anonymous.
- Informed consent - to check whether the ICF is compliant with MGCP.
- Compensation - to assess whether the subjects are being compensated appropriately, particularly the amount and the method of payment, so that the compensation does not unduly influence the subjects to participate in the study.

8.3 The review time of a new study from the receipt of an application by the secretariat to the MREC Chair's first decision is 60 working days. Decisions that the Chair can make are as follows:

- Expedited approval
- Further actions needed
- Table for full board meeting

## 9.0 MREC MEETING WORKFLOW

9.1 **Regular Meeting Schedule**

- The closing date for applications to be considered at an MREC meeting for the month shall normally be the end of the first week of the month.
- If there are less than 3 working days in the first week of the month, then the closing date may be moved to the second week of the month.
- Applications received after the closing date shall be considered at the next scheduled meeting.
- The MREC meeting shall normally be conducted once a month except that there shall be no meeting in December. More meetings will be held if required.

- The meeting schedule and application deadline is shown on the MREC application website and updated yearly.

9.2 **Notification and Distribution of the Meeting Agenda**

- The secretariat sends reminders to all MREC committee members of the scheduled and additional meetings at least 3 working days before the meeting, stating the date, time and the venue of each meeting.
- The secretariat sends minutes of the previous meeting and the meeting agenda of the upcoming meeting including the list of studies tabled for meeting.
- The MREC committee members can view online, details of studies to be tabled for a meeting. They can review the studies online at any time before the meeting.
- The secretariat will also notify PIs of studies which are tabled for meeting at least 3 working days before the meeting. They will be asked to stand-by in case their input is required. They will be informed of the time, date, and venue (or link in the event of a videoconference call).

9.3 **Preparation of members' meeting folders, study protocols and study protocol-related submissions scheduled for review**

- The secretariat creates a meeting-specific OneDrive folder which contains the following documents:
  a) The Meeting Agenda of the current meeting
  b) The Minutes of the previous meeting
  c) A list of studies tabled for the current meeting
  d) The RAFs completed by the Primary Reviewers
  e) The protocol and PIS of the above-mentioned studies
  f) The SAE report produced by the SAE subcommittee
  g) Other items necessary for the meeting
- The secretariat makes copies of the meeting agenda of the current meeting, which are distributed to the MREC members during the meeting. A summary RAF is used to capture the consensus decision.

- Study protocols and protocol-related documents that are available for the members to review online are projected onto a screen during the meeting.
- Distributed copies of the meeting agenda shall be collected after the meeting and shredded.
- The summary RAF is collected at the end of the meeting and filed.

9.4 **Determination of quorum**

- Quorum is defined as the presence of at least five of the MREC Committee Members and shall comprise of:
  a) at least one scientific/medical member
  b) at least one lay member
  c) at least one non-institutional member
  d) both male and female members
- Opinion and recommendations of a paediatrician should be available for studies that involve children.
- On the appointed meeting time, the Secretary determines whether there is a quorum and informs the Chair to indicate readiness to call the meeting to order.

9.5 **Calling the meeting to order and completion of required procedures prior to review proper**

- The Chair or the designated member in the Chair's absence calls the meeting to order upon confirmation of quorum by the Secretary.
- The Chair of MREC can allow an observer to be present in the meeting but the observer shall not be entitled to vote. All observers shall sign a confidentiality agreement regarding meeting deliberations, research information and other meeting matters prior to attending a meeting.
- The Secretary records the proceedings of the meeting, including the decisions made and reasons for said decisions in the meeting minutes. The Secretary documents the proceedings in the online system after the meeting.

- The Chair calls for declaration of Conflict of Interest (COI) in respect of any study scheduled for review. All declared COIs are documented by the secretariat staff.
- The Chair then presides over the review of the minutes of the previous meeting.
- The Chair proceeds to facilitate discussion of matters arising from the minutes, the discussions are noted by the secretariat staff for inclusion in the minutes of the current meeting.
- The Chair next proceeds to facilitate the review of new study applications which are tabled for the meeting.
- The Chair instructs any member who had declared COI to recuse himself/herself from the discussion and decision on any study for which the conflict was declared. Such members may be called to provide information to assist the committee to arrive at a decision, but under no circumstances participate in the decision.

9.6 **Discussion of New Study Applications and the conduct of PI interview**

- Based on the recommendations of relevant primary reviewers, PIs or their Co-Investigators of studies tabled for a full board meeting, may have to attend the meeting for an interview session.
- During the full board meeting, each PI will be asked to briefly describe the study protocol. Studies are reviewed guided by the Review Assessment Form (RAF) submitted by the primary reviewers.
- After the interview, the committee will discuss and come to a decision. The decision will be based on a simple majority of the members present at the meeting. In the event of a tie, the Chair will cast the deciding vote. The possible decisions are as follows:
  a) Approve
  b) Decision deferred pending minor modifications. Final decision by expedited review
  c) Decision deferred pending major modifications. Final decision by full board review either through a meeting or electronic mail
  d) Disapprove

- The Secretary is a non-voting member, but he/she is allowed to give comments and opinions.
- The MREC may invite independent consultants with expertise in special areas for assistance but the invitee shall not be entitled to vote.

9.7 **Notification of MREC's decision**

- All MREC decisions on new studies shall be documented in the online system by the Secretary.
- A notification email will be automatically generated by the system and sent to the PI once the Secretary has inputted the decision into the system. The inputting of the decision will be done within 7 working days of the most recent decision made (either by expedited review or full board review).
- For approved/rejected study, the PI has to login to their application account to access the decision letter.
- The decision letter includes the following information:
  a) Study title
  b) Name of PI
  c) MREC ID Number
  d) The documents reviewed
  e) The date of the MREC meeting (Not applicable for expedited review)
  f) The decision of review
  g) The date of decision
  h) Comments for the decision made
  i) The names and designations of MREC members involved in the decision (Not applicable for expedited review)
  j) Post approval instructions for PI including validity period of an approval
- For clinical trials, the PIs need to register the study with the National Medical Research Registry (www.nmrr.gov.my) before they will be able to generate the approval letter.
- For studies that require modification, the PIs will be notified by email to access the online system for submission of the required revision.

All revisions and other necessary documents/information shall be submitted via the online system. The Chair or Deputy Chair shall review all submitted revisions and decide whether to give expedited approval or to table it in next MREC meeting.

- For studies that are rejected, the PIs have to submit a new application with the revised documents through the iResearch portal.
- If errors are detected in the decision letter, the PIs can request the MREC Secretariat to amend and reissue the decision letter. MREC Secretariat shall keep a record of versions of the initial and corrected letters.

9.8 **Reports of expedited approval to Modified Pending Protocols**

- The Chair reports at a MREC meeting, all expedited approvals of revised study documents.
- The Chair shall ask the MREC members to endorse or comment on those expedited approvals.

9.9 **Report of Expedited Review**

- The Chair reports during the MREC meetings, all the studies that were approved via expedited review.
- The Chair shall ask the MREC members to endorse or comment on those expedited approvals.

9.10 **Study Protocol Amendment application**

- The Chair will present during the MREC meetings, a list of protocol amendment applications that have been granted expedited approval. MREC members will be asked to endorse or comment on those expedited approvals.
- Protocol amendments that are tabled for full board meeting will be discussed among MREC members to come to any of the following decisions:
  - Approve
  - Decision pending submission of additional information

- Revisions required
- Reject

- The PI will be called for an interview if the amendments are likely to affect subjects' safety.

9.11 **Review of Annual Study Report**

- The Chair will present during the MREC meetings, a list of annual study reports that have been granted expedited approval. MREC members will be asked to endorse or comment on those expedited approvals.
- Annual study reports that are tabled for full board meeting will be discussed among MREC members to come to any of the following decisions:
  - Approve
  - Decision pending submission of additional information
  - Revisions required
- The PI will be called for an interview if deemed necessary (e.g. poor progress or safety concerns).

9.12 **Review of Study Closure Report**

- The Chair will present during the MREC meetings, a list of study closure reports that have been granted expedited approval. MREC members will be asked to endorse or comment on those expedited approvals.
- Study closure reports that are tabled for full board meeting will be discussed among MREC members to come to any of the following actions:
  - Approve
  - Decision pending submission of additional information
  - Revisions required
- The PI will be called for an interview if deemed necessary.

9.13 **Review of Early Study Termination Application**

- The Chair presents the early study termination applications of previously approved studies during MREC meetings.
- The Chair calls on the committee members to discuss and recommend any of the following actions:
  - Approve
  - Decision pending submission of additional information
  - Further action required
- The PI will be called for an interview if deemed necessary.

9.14 **Review of Site Visits Report**

- The Chair of the Site Visit Sub-committee will present during the MREC meetings, a report on any site visits that have been conducted.
- The MREC Chair calls on the committee members to discuss and recommend any of the following actions:
  - No further action
  - Decision pending submission of more information
  - Further action required

9.15 **Review of Study Protocol Non-compliance (Deviation or Violation) Report**

- The Chair calls on the committee members to discuss and recommend any of the following actions:
  - No further action
  - Decision pending submission of more information
  - Further action required

9.16 **Review of Queries, Notifications and Complaints**

- The Chair presents during the MREC meetings any Queries, Notifications and Complaints received.
- The Chair calls on the committee members to discuss and recommend any of the following actions:
  - No further action
  - Decision pending submission of more information

- Further action required

9.17 **Review of Serious Adverse Events (SAE) report**

- The Chair of the Serious Adverse Events (SAE) Subcommittee presents during the MREC meetings any report of the SAE Subcommittee. The Chair calls on the UMMC-MREC members to deliberate on the recommendations of the SAE Subcommittee and decide on the following actions:
  - No further action
  - Decision pending submission of more information
  - Further action required

9.18 **Adjournment of the meeting**

- Before closing the meeting, the Chair calls for the discussion of any non-study matters that need attention or action.
- If there is no further matter for discussion, the Chair formally adjourns the meeting, with the time noted by the Secretariat Staff who is documenting the meeting.

9.19 **Collection and storage or disposal of meeting materials**

- The secretary will collect all meeting materials, including the distributed minutes of previous meeting, the current meeting agenda and other documentation used for the current meeting.
- The secretary files all meeting materials and stores the files according to SOP4. Files that are not needed any more are destroyed.

## 10.0 SPECIAL MEETING WORKFLOW

10.1 **Preparation for Conducts of Special Meeting**

- A special meeting may be called by the Chair or proposed by a MREC member or the Director of the UMMC.

- A special meeting is called based on the following criteria:
  - Urgent issues that if action is delayed will affect or impact public benefit, national economy, etc.
  - Occurrence of unexpected serious adverse events
  - Matters of life and death
  - Other similar situations
- The Secretariat will inform the MREC members, including any invited persons, about the special meeting.

10.2 **Conduct of Special Meeting**

- Quorum is defined as the presence of at least five MREC committee members described as follows:
  - At least one scientific/medical member
  - A non-scientific member or lay person
  - At least one non-institutional member
  - A member/or invited guest with expertise on the item to be discussed
- A special meeting may be conducted through tele/video conference.
- The meeting is conducted in the same process as a normal MREC meeting with similar decisions (where applicable) to be taken.
- In the event a meeting cannot be held, a decision may be made through consensus via electronic mail.

10.3 **Collection and Storage or Disposal of Meeting Materials**

- The Secretariat Staff collects all meeting materials after the meeting is over.
- The materials are then managed as per section 9.19 above.

**APPENDIX 1**

# REVIEW ASSESSMENT FORM
# UMMC-MREC

**MREC ID:**
**STUDY TITLE:**
**Principal Investigator:**
**Primary Reviewers: SCIENTIFIC: ; NON-SCIENTIFIC:**
**Date of UMMC-MREC meeting:**

**PART A: REVIEW OF RESEARCH PROTOCOL (SCIENTIFIC MEMBER ONLY)**
** **Ref**: You may refer to the relevant question(s) in the online application form submitted by the researcher.*
*****Y**: Yes; **N**: No; **NA**: Not Applicable*

| No. | Assessment Criteria for Protocol | *Ref | **Y / N / NA | Comments |
|---|---|---|---|---|
| **Suitability of Investigators** | | | | |
| 1 | Do the investigators have the necessary experience and skills to conduct the study? | 12,15 | | |
| 2 | Is there a physician (or dentist when appropriate) in the study team who is responsible for study related medical decisions? | 12,15 | | |
| **Adequacy of Background Information** | | | | |
| 3 | Is there acceptable information on the investigational product(s) where appropriate? | 35 | | |
| 4 | Is there a clear summary of available non-clinical and clinical information relevant to the study? | 17 | | |
| 5 | Is there a clear summary of the known and potential risks and benefits to subjects? | 41, 42 | | |
| 6 | Is there acceptable review of the study treatment(s) especially route of administration, dosage, dosage regimen and treatment period? | 24 | | |
| 7 | Is there a clear description of the study population? | 24, 31 | | |
| 8 | Is the literature review current and appropriate? | 24 | | |
| **Project Information** | | | | |

| | | | | |
|---|---|---|---|---|
| 9 | Are the objectives and outcomes clear? | 20 | | |
| 10 | Does this study answer an important question? | 19 | | |
| 11 | Have similar studies been done before? | 18 | | |
| **Study Design** | | | | |
| 12 | Are the study endpoints stated? | 21 | | |
| 13 | Is the study design appropriate? Is there a schematic diagram of the study design? | 24 | | |
| 14 | Is there a description of how bias is minimized, including randomization, and blinding? | 24 | | |
| 15 | Is it stated how randomization codes are maintained and procedure for breaking code? | 24 | | |
| 16 | Is the expected duration of subjects' participation, and description of the sequence and duration of study periods, acceptable? | 34 | | |
| 17 | Are stopping rules or discontinuation criteria for study, stated? | 24 | | |
| 18 | Are the accountability procedures for the investigational product(s), stated? | 24 | | |
| **Selection and Withdrawal of Subjects** | | | | |
| 19 | Are subject inclusion and exclusion criteria, acceptable? | 31 | | |
| 20a | Does the study involve vulnerable subjects? | 30 | | |
| 20b | Are steps taken to ensure they are not being disadvantaged? | 30 | | |
| 21 | Are subject withdrawal criteria, stated? | 24 | | |
| **Study Treatment** | | | | |
| 22 | Is there acceptable information on all treatment(s) administered, dose, dosing schedule, route of administration, and treatment periods? | 24 | | |

| | | | | |
|---|---|---|---|---|
| 23 | Are permitted and not permitted medications/treatments before and during study period, clearly stated? | 36 | | |
| 24 | Is there information on how compliance of subjects is monitored? | 24 | | |
| **Assessment of Efficacy** | | | | |
| 25 | Are efficacy parameters specified? | 24 | | |
| 26 | Are methods and timing for assessing, recording, and analysis of efficacy parameters, stated? | 24 | | |
| **Assessment of Safety** | | | | |
| 27 | Are safety parameters specified? | 24 | | |
| 28 | Are methods and timings for assessing, recording, and analyzing safety parameters, stated? | 24 | | |
| 29 | Are procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses, stated? | 24 | | |
| 30 | Are the type and duration of follow-up of subjects after adverse events, stated? | 24 | | |
| **Statistics** | | | | |
| 31 | Is the statistical method for analysis, described? | 29 | | |
| 32 | Is the number of subjects planned to be enrolled, acceptable? | 29 | | |
| **Direct Access to Source Data** | | | | |
| 33 | Is it stated who are the individuals who have direct access to source data? | 46 | | |
| **Ethical Issues** | | | | |
| 34 | Are there benefits to the subjects? | 41 | | |
| 35 | a. Are risks to the subjects acceptable? | 42 | | |

| | | | | |
|---|---|---|---|---|
| | b. Are actions taken to minimize them? | | | |
| 36 | Are the participants' information anonymized? | 44 | | |
| | Is the data kept securely? | | | |
| 37 | Are the subjects compensated appropriately? | 54 | | |
| 38 | Is Data Handling and Record Keeping acceptable? | 45, 46 | | |
| 39 | Is the storage period of data/ records acceptable? | 47 | | |
| **Study Insurance** | | | | |
| 40 | Is there insurance to pay for treatment of study-related injuries? | 55 | | |

**PART B: REVIEW OF PARTICIPANT INFORMATION SHEET (NON-SCIENTIFIC MEMBER)**

** **Ref**: You may refer to the relevant question(s) in the online application form submitted by the researcher.*

*****Y**: Yes; **N**: No; **NA**: Not Applicable*

| No. | Assessment Criteria for Protocol | *Ref | **Y / N / NA | Comments |
|---|---|---|---|---|
| 1 | Is it stated that the study involves research? | Intro | | |
| 2 | Is the purpose of the study stated clearly? | 1 | | |
| 3 | Are the study treatment(s), possibility of randomization and blinding stated clearly? | 3 | | |
| 4 | Is the information on study procedures, especially invasive ones, acceptable? | 4 | | |
| 5 | Are subjects' responsibilities stated clearly? | 9 | | |
| 6 | Is it stated which aspects of the study are experimental? | - | | |
| 7 | Is the information on foreseeable risks and | 11 | | |

| | | | | |
|---|---|---|---|---|
| | inconveniences to the subjects acceptable? | | | |
| 8 | Are the expected benefits stated? | 12 | | |
| 9 | Are alternate procedures or treatments stated if patients do not consent to participate? | 16 | | |
| 10 | Is the information on compensation and treatment for study-related injuries appropriate? | - | | |
| 11a | Is the prorated payment for participation clearly stated? | - | | |
| 11b | Is the amount acceptable? | - | | |
| 12 | Is there information on the anticipated expenses to the subject for participating in the study? | - | | |
| 13 | Is it stated that participation of the subject is voluntary and that the subject may refuse to participate or withdraw from the study without any penalty or loss of benefits? | 8, 16 | | |
| 14 | Is there acceptable information on the individuals who have access to the subject's medical records and study data? | 13 | | |
| 15 | Is there acceptable information on how confidentiality of the subjects' records can be ensured? | 14 | | |
| 16 | Is it stated that the subject will be informed of new information that may affect the subject's willingness to continue in the study? | 17 | | |
| 17 | Is there information on who the subject should contact for further information on the study, their rights as subjects, and reporting study-related injuries? | 22, 23 | | |

| | | | | |
|---|---|---|---|---|
| 18 | Is the circumstances or reasons for terminating a subject's participation stated clearly? | - | | |
| 19 | Is the expected duration of the subject's participation stated? | 10 | | |
| 20 | Is the number of subjects in the study stated? | - | | |
| 21 | Is there information on whether the source(s) and component(s) of the investigational product are culturally acceptable? | 5 | | |
| 22 | Is the language of the PIS understandable? | - | | |
| 23 | Is the language of the consent form understandable? | - | | |
| 24 | Is the procedure for obtaining informed consent appropriate? | - | | |

**PART C: REVIEWERS' COMMENTS**
**Should the researcher be interviewed?** Yes / No

**Brief account of the study and its objectives (by Scientific Primary Reviewer only):**

**Points of note or concern:**

1. **Scientific Primary Reviewer:**

2. **Non-Scientific Primary Reviewer:**

**Recommendation:**

1. **Scientific Primary Reviewer:**

2. **Non-Scientific Primary Reviewer:**

**Scientific Primary Reviewer (Name):** **Date of review:**
**Non-Scientific Primary Reviewer (Name):** **Date of review:**

**PART D: SECRETARY'S NOTES**

**PART E: DECISION BY MREC: Accept/ Modify/ Reject**

**Chair (Name):**

**APPENDIX 2**

**Summary of MREC Review and Decision**

**MREC ID No.:** **Protocol No. (if applicable):**
**Study title:**
**Principal Investigator:**
**Primary reviewers:**
**Date of UMMC-MREC Meeting:**

| No | Assessment Criteria | Acceptable | Not acceptable | Not applicable | Comments |
|---|---|---|---|---|---|
| | | | | | |
| 1 | **Suitability of investigators** | | | | |
| 2 | **Adequacy of background Information** (investigational product, scientific information, risks and benefits, details of study treatment, study population. literature review) | | | | |
| 3 | **Project Information (**Objectives and outcomes; importance of research question, study justification) | | | | |
| 4 | **Study Design** (Scientific rigour, participation duration, stop and discontinuation criteria, accountability procedures) | | | | |
| 5 | **Selection and Withdrawal of Subjects** (Inclusion and exclusion criteria, vulnerable population, disadvantaged subjects, withdrawal criteria, rescue mechanisms) | | | | |
| 6 | **Study Treatment** (Treatment information, community sensitivities, monitoring of compliance) | | | | |
| 7 | **Efficacy** (efficacy parameters, assessment and analysis) | | | | |
| 8 | **Safety** (safety assessment and analysis; adverse event reporting, duration of follow up). | | | | |
| 9 | **Statistics** (Statistical method; sample size) | | | | |
| 10 | **Access to Data** (Who has direct access to source data) | | | | |
| 11 | **Ethical Issues (**Benefits and risks; confidentiality, compensation, data security ) | | | | |
| 12 | **Study Insurance** | | | | |
| 13 | **Informed consent and participant information sheet** | | | | |

**Decision and Comment:** Approve / Modify / Reject Vote count:

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**Name of Chairman:** **Signature:**