|  |
| --- |
| **Minutes of the NAME OF** **­­REGULAR MEETING****<dd/mm/yyyy>, Venue, Time** |

**ATTENDANCE**

|  |  |
| --- | --- |
| **PRESENT** | **ABSENT** |
| Member 1Member 2Member 3Member 4Member 5Member 6Member 7Others:Panel Staff | Member 1Member 2 |

1. **PRAYER**
2. **DETERMINATION OF QUORUM**

A quorum was declared with the presence of <number> members, inclusive of the presence of <number> institutional and <number> non-institutional members, in which <number> are male and <number> are female, as confirmed by the Member-Secretary, <Title, Name, Surname>.

1. **CALL TO ORDER**

Title, First Name, Surname>, RERC Chair, called this regular meeting to order at <time> AM.

1. **DISCLOSURE OF CONFLICT OF INTEREST**

<Title, Surname of RERC Chair>, called for disclosure of Conflict of Interest (COI) in the Study Protocols scheduled for deliberation in the meeting. The following member/s are inhibited from participation in the panel deliberations during the full board meeting for the following reasons:

<Title, Name, Surname> as Principal Investigator for the study entitled, “TITLE” (STUDY PROTOCOL NUMBER)

1. **READING AND APPROVAL OF THE MINUTES OF THE LAST MEETING**

<Title, Surname of Chair>presided over the discussion of the minutes of the **(RERC REVIEW)** meeting held last <dd/mm/yyyy> (**Date of last meeting).** <Title, Name, Surname> moved for the approval of minutes with no/minor corrections. It was seconded by <Title, Name, Surname>. The minutes were corrected during the discussion and approved as amended.

**5.1 Business Arising from the Minutes of the Last Meeting**

5.1.1 Corrections in the Minutes

5.1.2 Matters requiring MMMC-RERC action

1. **APPROVAL OF MEETING AGENDA**
2. **STUDY PROTOCOL REVIEW**
	1. **FULL REVIEW**
		1. **Study Protocols for Initial Review**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Sponsor/CRO |  |
| Quorum status |  |
| Conflict of interest |  |
| Assessment of scientific soundness | 1. **Objectives/Expected output**
2. **Literature review**
3. **Research design**
4. **Sampling design, sample size**
5. **Inclusion criteria, exclusion criteria, withdrawal criteria**
6. **Specimen collection and processing**
7. **Statistical and data analysis plan**
8. **PI qualifications**
9. **Suitability and choice of site**
10. **Validation of research instruments among Filipino participants**
 |
| Assessment of ethical issues | 1. **Conflict of Interest:**
2. **Privacy and confidentiality including data protection plan**
3. **Vulnerability**
4. **Risks**
5. **Benefits**
6. **Informed consent process and recruitment:**
7. **Informed Consent Form (ICF) (including translation)**
8. **Documentation of collaborative study TOR**
 |
| Conclusion and recommendations |  |
| Action taken | **Decision:*** Approved
* Major Modification, which require full board deliberation
* Minor Modification, which can be expedited at the level of the Panel Chair
* Request for information
* Disapproved

**Votes:**  |
| Approval expiration date (if applicable) |  |
| Frequency of continuing review (in case of approval |  |
| Reasons  |  |

* + 1. **Resubmissions or Study Protocols for Modification**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Resubmission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Quorum status |  |
| Conflict of Interest |  |
| ***Assessment of PI response to initial review*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision:*** Approved
* Major Modification, which require full board deliberation
* Minor Modification, which can be expedited at the level of the Chair
* Disapproved

**Votes:** |
| Approval expiration date (if applicable) |  |
| Frequency of continuing review (in case of approval |  |
| Reasons |  |

* + 1. **Study Protocols for Clarificatory Interview**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of PI responses to queries*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision:** (Decisions are based on the assessment of the PI’s response to their queries); **Votes:** |
| Reasons |  |

* + 1. **Withdrawal of Study Protocol Applications**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Withdrawal Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of reasons for Study Protocol withdrawal*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision:*** Approved
* Request information
* Recommend further action

**Votes:** |
| Reasons |  |

* + 1. **Study Protocol Amendment Applications**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Amendment Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of amendment requested*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision:*** Approved
* Minor modification to the study protocol amendment, citing reasons for action, subject to expedited review at the level of the Chair
* Major modification to the study protocol amendment, stating reasons for action, subject to full board review
* Disapproved

**Votes:** |
| Reasons |  |

* + 1. **Continuing Review Applications**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of continuing review application*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision:*** Approved
* Request information
* Recommend further action

**Votes:** |
| Reasons |  |

* + 1. **Progress Reports**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of progress report*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision Points:*** Approved
* Request information
* Recommend further action

**Votes:** |
| Reasons |  |

* + 1. **Final Reports**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of final report*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision Points:*** Approved
* Request information
* No further action required
* Recommend further action

**Votes:** |
| Reasons |  |

* + 1. **Study Protocol Non-Compliance (Deviation or Violation) Reports**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of Non-Compliance Report 1:*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision:*** No further action required
* Request information
* Recommend further action

**Votes:** |
| Reasons |  |
| ***Assessment of Non-Compliance Report 2:*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision:*** No further action required
* Request information
* Recommend further action

**Votes:** |
| Reasons |  |
| ***Assessment of Non-Compliance Report 3:*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision:*** No further action required
* Request information
* Recommend further action

**Votes:** |
| Reasons |  |

* + 1. **Early Study Termination Applications**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of risks from early termination*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision:*** Approved
* Request information
* Recommend further action
 |
| Reasons |  |

* + 1. **Queries, Notifications and Complaints from Various Stakeholders**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of query or complaint/ notification*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision:*** No further action
* Request information
* Recommend further action

**Votes:** |
| Reasons |  |

* + 1. **SAE and SUSAR Reports**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of SAEs reported*** |  |
| SAE 1 | Submission Date | <dd/mm/yyyy> |
| Date of SAE | <dd/mm/yyyy> |
| Date of randomization | <dd/mm/yyyy> |
| Age |  |
| Sex |  |
| Country |  |
| Nature of AE |  |
| Co-morbidities |  |
| Status |  |
| Recommendations by Primary Reviewers and Chair | **Recommendation:*** No modifications required, study to continue
* Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks
* Recommend implementation of additional procedures for protecting/ safeguarding participants
* Suspension of enrolment of new participants or research procedures among participants who are currently enrolled (check consistency)
* Recommend suspension of the entire study)

**Votes:** |
| Action taken | **Decision:*** No further action required
* Request information
* Recommend further action

**Votes:**  |
| Reasons |  |
| SAE 2 | Submission Date | <dd/mm/yyyy> |
| Date of SAE | <dd/mm/yyyy> |
| Date of randomization | <dd/mm/yyyy> |
| Age |  |
| Sex |  |
| Country |  |
| Nature of SAE |  |
| Co-morbidities |  |
| Status |  |
| Recommendations by Primary Reviewers and Chair | **Recommendation:*** No modifications required, study to continue
* Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks
* Recommend implementation of additional procedures for protecting/ safeguarding participants
* Suspension of enrolment of new participants or research procedures among participants who are currently enrolled (check consistency)
* Recommend suspension of the entire study)

**Votes:** |
| Action taken | **Decision:*** No further action required
* Request information
* Recommend further action

**Votes:**  |
| Reasons |  |

* + 1. **DSMC/ DSMB/ IDMC**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of DSMC/ DSMB/ IDMC*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision:*** No further action
* Recommend further action
* Request information
* Approved

**Votes:** |
| Reasons |  |

* + 1. **Site Visit Reports**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Site Visit Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of Site Visit Report*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision:*** No further action required
* Request information
* Recommend further action

**Votes:** |
| Reasons |  |

* 1. **REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW AND FULL BOARD PROTOCOLS WITH MODIFICATION EXPEDITED AT THE LEVEL OF THE CHAIR**
		1. **Approved Protocols**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |

* + 1. **Study Protocols for Initial Review**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Action taken | **Decision:*** Approved
* Major Modification, which require full board deliberation
* Minor Modification, which can be expedited at the level of the Chair
* Disapproved
 |

* + 1. **Resubmissions (study protocols for modification)**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Action taken | **Decision:*** Approved
* Major Modification, which require full board deliberation
* Minor Modification, which can be expedited at the level of the Chair
* Disapproved
 |

* + 1. **Study Protocol Amendments**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Date of Amendment Submission | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Action taken | **Decision:*** Approved
* Minor modification to the study protocol amendment, citing reasons for action, subject to expedited review at the level of the Chair
* Major modification to the study protocol amendment, stating reasons for action, subject to full board review
* Disapproved
 |

* + 1. **Continuing Review Applications**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Date of Report | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Action taken | **Decision:*** Approved
* Request information
* Recommend further action
 |

* + 1. **Final Reports**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Date of Report | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Action taken | **Decision:*** Approved
* Request information
* Recommend further action
 |

* + 1. **Study Protocol Non-Compliance (Deviation or Violation) Reports**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Date of Report | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Action taken | **Decision:*** No further action
* Request information
* Recommend further action
 |

* + 1. **Early Study Termination Applications**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Action taken | **Decision:*** Approved
* Request information
* Recommend further action
 |

* + 1. **Queries, Notifications, and Complaints**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Sponsor/CRO |  |
| Action taken | **Decision:*** No further action
* Recommend further action
* Request information
 |

1. **OTHER MATTERS**
2. **ADJOURNMENT**

Meeting was adjourned at**<time**>. The next meeting will be on **<date>**

|  |  |  |
| --- | --- | --- |
| Prepared by: | Signature over <Title, Name, Surname> |  |
| DATE: <dd/mm/yyyy> | ADMINISTRATIVE STAFF |  |
| Checked by: | Signature over <Title, Name, Surname> |  |
| DATE: <dd/mm/yyyy> | MEMBER-SECRETARY |  |
| Approved by: | Signature over <Title, Name, Surname> |  |
| DATE: <dd/mm/yyyy> | CHAIR |  |