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

**ATTENDANCE**

|  |  |
| --- | --- |
| **PRESENT** | **ABSENT** |
| Member 1  Member 2  Member 3  Member 4  Member 5  Member 6  Member 7  Member 8  Member 9  Others:  Panel Staff |  |

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. **APPROVAL OF MEETING AGENDA**
2. **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. **CALL TO ORDER**

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

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.

* 1. **Business Arising from the Minutes of the Last Meeting**
     1. Corrections in the Minutes
     2. Matters requiring MMMC-RERC action

1. **STUDY PROTOCOL REVIEW**
   1. **FULL REVIEW**
      1. **Study Protocols for Initial Review**

|  |  |  |
| --- | --- | --- |
| MMMC-RERC Code |  | |
| SJREB 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 |  |
| SJREB 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 |  |
| SJREB 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 |  |
| SJREB 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 |  |
| SJREB 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 |  |
| SJREB 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 |  |
| SJREB 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 |  |
| SJREB 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 |  |
| SJREB 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:**  Acknowledged/No further action required  Study to continue but will monitor compliance  Request information  Recommend further action  **Votes:** |
| Reasons |  |
| ***Assessment of Non-Compliance Report 2:*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision:**  Acknowledged/No further action required  Study to continue but will monitor compliance  Request information  Recommend further action  **Votes:** |
| Reasons |  |
| ***Assessment of Non-Compliance Report 3:*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision:**  Acknowledged/No further action required  Study to continue but will monitor compliance  Request information  Recommend further action  **Votes:** |
| Reasons |  |

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

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| SJREB 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  **Votes:** |
| Reasons |  |

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

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| SJREB 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 |  | |
| SJREB 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 |  |
| SJREB 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:**  Approved  No further action  Recommend further action  Request information  **Votes:** |
| Reasons |  |

* + 1. **Site Visit Reports**

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

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

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

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

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

* + 1. **Study Protocol Amendments**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| SJREB 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 |  |
| Remarks/Description |  |
| Action taken | **Decision:**  Approved  Major Modification, which require full board deliberation  Minor Modification, which can be expedited at the level of the Chair  Disapproved |
| Approval Date |  |

* + 1. **Continuing Review Applications**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| SJREB 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 |  |
| Remarks/Description |  |
| Action taken | **Decision:**  Approved  Request information  Recommend further action |
| Approval Date |  |

* + 1. **Final Reports**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| SJREB 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 |  |
| Remarks/Description |  |
| Action taken | **Decision:**  Approved  Request information  Recommend further action |
| Approval Date |  |

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

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| SJREB 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 |  |
| Remarks/Description |  |
| Action taken | **Decision:**  Acknowledged/No further action required  Study to continue but will monitor compliance  Request information  Recommend further action |
| Approval Date |  |

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

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| SJREB 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 |  |
| Remarks/Description |  |
| Action taken | **Decision:**  Approved  Request information  Recommend further action |
| Approval Date |  |

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

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| SJREB 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 |  |
| Remarks/Description |  |
| Action taken | **Decision:**  No further action  Recommend further action  Request information |
| Approval Date |  |

* + 1. **SAE and SUSARs**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| SJREB 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 |  |
| Remarks/Description |  |
| Action taken | **Decision:**  No further action  Recommend further action  Request information |
| Approval Date |  |

* 1. **Exempt from Review**

|  |  |
| --- | --- |
| MMMC-RERC Code |  |
| SJREB 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 |  |
| Remarks/Description |  |
| Action taken | **Decision:**  No further action  Recommend further action  Request information |
| Approval Date |  |

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> | CHAIRMAN |  |