|  |
| --- |
| **Minutes of the Full Board Meeting**  **­­<ordinal> <REGULAR/SPECIAL> MEETING**  **<mm/dd/yyyy>, Venue, Time** |

1. **ATTENDANCE**

|  |  |
| --- | --- |
| **PRESENT** | **ABSENT** |
| Member 1  Member 2  Member 3  Member 4  Member 5  Member 6  Member 7  Others:  Staff | Name1  Name2 |

1. **CALL TO ORDER**

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

1. **DETERMINATION OF QUORUM**

A quorum was declared with the presence of <number> members, inclusive of the presence of <number> non-institutional and <number> lay members, and as confirmed by the Secretary, <Title, Name, Surname>.

1. **APPROVAL OF THE AGENDA**

<Title, Surname of Chair>, presided over the presentation of the Agenda and called for the Approval of the Agenda of the <Regular/Special> Meeting. <Title, Name, Surname> moved for the Approval of the Agenda, and was seconded by <Title, Name, Surname>.

1. **DISCLOSURE OF CONFLICT OF INTEREST**

<Title, Surname of Chair>, called for disclosure of Conflict of Interest (COI) in the Study Protocols scheduled for deliberation in the meeting. The following member/s inhibited from participation in the 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 **FEU-NRMF IERC** meeting held last <mm/dd/yyyy> (**Date of last meeting).** The minutes were corrected during the discussion and approved as amended. <Title, Surname of Chair>, called for the Approval of the Minutes of the Last Meeting. <Title, Name, Surname> moved for the Approval of the Minutes, and was seconded by <Title, Name, Surname>.

1. **BUSINESS ARISING FROM THE MINUTES OF THE LAST MEETING**
   1. Corrections in the Minutes
   2. Matters requiring FEU-NRMF IERC action
2. **STUDY PROTOCOL REVIEW**
   1. **FULL REVIEW**
      1. **Study Protocols for Initial Review and Clarificatory Interview**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Submission Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review |  |
| Sponsor |  |
| 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** |
| ***Assessment of PI responses to queries*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision** (Approval, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the level of the Chair, Disapproval) |

* + 1. **Resubmissions or Study Protocols for Modification and Clarificatory Interview**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Submission Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Quorum status |  |
| Conflict of Interest |  |
| ***Assessment of PI response to initial review*** |  |
| ***Assessment of PI responses to queries*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision** (Approval, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the level of the Chair, Disapproval) |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Submission Date | <mm/dd/yyyy> |
| Withdrawal Application Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Amendment Submission Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of amendment requested*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision** (Approval, Minor modification to the proposed amendment, citing reasons for action, subject to expedited review at the level of the Chair, Major modification to the proposed amendment, stating reasons for action, subject to full board review, Disapproval) |

* + 1. **Progress Report Applications:**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Application Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of progress reported*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision** (Uphold original approval with no further action, Request information, Recommend further action) |

* + 1. **Continuing Review Applications:**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Application Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of progress reported*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision** (Uphold original approval with no further action, Request information, Recommend further action) |

* + 1. **Final Reports**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Report Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of final report*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision Points** (Approve, Request information, Recommend further action) |

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

|  |  |  |
| --- | --- | --- |
| FEU-NRMF IERC Code |  | |
| Study Protocol Approval Date | <mm/dd/yyyy> | |
| Report Date | <mm/dd/yyyy> | |
| Study Protocol Title |  | |
| Principal Investigator |  | |
| Type of Review |  | |
| Primary Reviewers |  | |
| Technical Review |  | |
| Sponsor |  | |
| Quorum status |  | |
| Conflict of Interest: |  | |
| ***Assessment of SAEs reported*** |  | |
| SAE 1 | Submission Date | <mm/dd/yyyy> |
| Date of SAE | <mm/dd/yyyy> |
| Date of randomization | <mm/dd/yyyy> |
| Age |  |
| Sex |  |
| Country |  |
| Nature of AE |  |
| Co-morbidities |  |
| Status |  |
| Conclusion and recommendations |  | |
| Action taken | **Decision Points** (Uphold original approval with no further action, Request information, Recommend further action) | |
| SAE 2 | Submission Date | <mm/dd/yyyy> |
| Date of SAE | <mm/dd/yyyy> |
| Date of randomization | <mm/dd/yyyy> |
| Age |  |
| Sex |  |
| Country |  |
| Nature of SAE |  |
| Co-morbidities |  |
| Status |  |
| Conclusion and recommendations |  | |
| Action taken | **Decision Points** (Uphold original approval with no further action, Request information, Recommend further action) | |

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

|  |  |  |  |
| --- | --- | --- | --- |
| FEU-NRMF IERC Code |  | | |
| Study Protocol Approval Date | <mm/dd/yyyy> | | |
| Date of Report | <mm/dd/yyyy> | | |
| Study Protocol Title |  | | |
| Principal Investigator |  | | |
| Type of Review |  | | |
| Primary Reviewers |  | | |
| Technical Review |  | | |
| Sponsor |  | | |
| Events | 1. | Event count |  |
|  | 2. | Event count |  |
| Nature of SAE (Total) | Expected |  | |
| Unexpected |  | |

* + 1. **Site Visit Reports**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Site Visit Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of Site Visit Report*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision Points (**Uphold original approval with no further action, Request information, Recommend further action) |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Report Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of Non-Compliance Report*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision** (Uphold original approval with no further action, Request information, Recommend further action) |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Application Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of risks from early termination*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision** (Approval, Request information, Recommend further action) |

* + 1. **Queries or Complaints**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Application Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of query or complaint*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision (**Uphold original approval with no further action, Request information, Recommend further action) |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Study Protocol Submission Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Action taken | **APPROVAL** |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Submission Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Action taken | **Decision** (Approval, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the level of the Chair, Disapproval) |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Submission Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Action taken | **Decision** (Approval, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the level of the Chair, Disapproval) |

* + 1. **Study Protocol Amendments**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Date of Amendment Submission | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Action taken | **Decision** (Approval, Minor modification to the proposed amendment, citing reasons for action, subject to expedited review at the level of the Chair, Major modification to the proposed amendment, stating reasons for action, subject to full board review, Disapproval) |

* + 1. **Progress Report Applications**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Date of Report | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Action taken | **Decision** (Uphold original approval with no further action, Request information, Recommend further action) |

* + 1. **Continuing Review Applications**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Date of Report | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Action taken | **Decision** (Uphold original approval with no further action, Request information, Recommend further action) |

* + 1. **Final Reports**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Date of Report | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Action taken | **Decision Points** (Approval, Recommend further action) |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Date of Report | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Action taken | **Decision** (Uphold original approval with no further action, Request information, Recommend further action) |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Application Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Action taken | **Decision** (Approval, Request information, Recommend further action) |

* + 1. **Queries or Complaints**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <mm/dd/yyyy> |
| Application Date | <mm/dd/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Sponsor |  |
| Action taken | **Decision (**Uphold original approval with no further action, Request information, Recommend further action) |

1. **Report of Protocol Submissions Classified as Exempted from Ethics Review**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Title |  |
| Principal investigator |  |

1. **OTHER MATTERS**
2. **SUMMARY OF REVIEWED PROTOCOLS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Full Board** | | **Expedited** | |
| **Type of Submission** | **Number** | **Type of Submission** | **Number** |
|  |  |  |  |
|  |  |  |  |
| **TOTAL** |  |  |  |

|  |  |
| --- | --- |
| **Exempted** |  |
| **Withdrawals** |  |

1. **ADJOURNMENT**

Meeting was adjourned at **<time>**

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