|  |  |
| --- | --- |
|  | **Far Eastern University – Dr. Nicanor Reyes Medical Foundation** **INSTITUTIONAL ETHICS REVIEW COMMITTEE** Rm 218, 2nd Floor, Institute of MedicineRegalado Avenue near Dahlia Street, West Fairview, Quezon City 1118Telefax: +63 (02) 8-9838338 loc 1236; Email: ierc@feu-nrmf.edu.ph |

Date of issuance: <mm/dd/yyyy>

## NOTICE OF <REGULAR/SPECIAL> MEETING

TO: **<NAME OF FEU-NRMF IERC Members>:**

 **Member 1**

 **Member 2**

 **Member 3**

 **Member 4**

 **Member 5**

 **Member 6**

 **Member 7**

 **Member 8**

DATE OF MEETING

TIME OF MEETING

VENUE OF MEETING

**AGENDA:**

1. **Call to order**
2. **Determination of quorum and presence of non-institutional members**
3. **Approval of the Meeting Agenda**
4. **Disclosure of Conflict of interest**
5. **Reading and approval of the Minutes of the last meeting**
6. **Business arising from the Minutes of the last meeting**
7. **Protocol review**
	1. **FULL REVIEW**
		1. **Study Protocols for Initial Review and Clarificatory Interview**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Withdrawal Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Amendment Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |

* + 1. **Progress Reports**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |

* + 1. **Continuing Review Applications**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |

* + 1. **Final Reports**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |

* + 1. **Early Study Termination Application**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |

* + 1. **Queries or Complaints**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |

* + 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 | <dd/mm/yyyy> |
| Site Visit Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |

* 1. **REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW AND FULL BOARD PROTOCOLS WITH MODIFICATION EXPEDITED AT THE LEVEL OF THE CHAIR**
	2. **REPORT OF PROTOCOL SUBMISSIONS CLASSIFIED AS EXEMPTED FROM ETHICS REVIEW**
1. **Other Matters**
2. **Adjournment**

Prepared by:

**<TITLE, NAME, SURNAME> and SIGNATURE**

Secretariat, FEU-NRMF IERC

**<TITLE, NAME, SURNAME> and SIGNATURE**

Secretary, FEU-NRMF IERC

Noted by:

**<TITLE, NAME, SURNAME> and SIGNATURE**

Chair, FEU-NRMF IERC

**ANNEX 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 | <dd/mm/yyyy> |
| Study Protocol Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |

1. **Study Protocols for Initial Review**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |
| **ACTION** |  |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |
| **ACTION** |  |

1. **Study Protocol Amendment Applications**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Amendment Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |
| **ACTION** |  |

1. **Progress Reports**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |
| **ACTION** |  |

1. **Continuing Review Applications**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |
| **ACTION** |  |

1. **Final Reports**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |
| **ACTION** |  |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |
| **ACTION** |  |

1. **Early Study Termination Applications**

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |
| **ACTION** |  |

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

|  |  |
| --- | --- |
| FEU-NRMF IERC Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review  |  |
| Funding agency/CRO |  |

**Annex 2**

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

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

Prepared by:

**<TITLE, NAME, SURNAME> and SIGNATURE**

Secretariat, FEU-NRMF IERC

**<TITLE, NAME, SURNAME> and SIGNATURE**

Secretary, FEU-NRMF IERC

Noted by:

**<TITLE, NAME, SURNAME> and SIGNATURE**

Chair, FEU-NRMF IERC