|  |  |
| --- | --- |
|  | **University of the Philippines Manila**  **RESEARCH ETHICS BOARD**  Room 126, National Institutes of Health, UP Manila  623 Pedro Gil Street, Ermita, 1000 Manila  *Telephone*: +63 2 8526-4346; *Email*: upmreb@post.upm.edu.ph |

Date of issuance: <dd Month yyyy>

## NOTICE OF MEETING

TO: **<NAME OF UPMREB REVIEW PANEL> Members:**

(Name1, position, exptertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)

(Name2, position, exptertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)

(Name3, position, exptertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)

(Name4, position, exptertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)

(Name5, position, exptertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)

(Name6, position, exptertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)

(Name7, position, exptertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)

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. **Disclosure of Conflict of interest**
4. **Approval of the Agenda of the Meeting**
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 (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Study Protocol Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Required expertise | <Pediatrics, Oncology, Dermatology, Rheumatology, Pulmonology, etc.> |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Time allotment |  |

* + 1. **Resubmissions or Study Protocols for Modification (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Study Protocol Resubmission Date | <dd/mm/yyyy> |
| Study Protocol Initial Submission Date |  |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Required expertise | <Pediatrics, Oncology, Dermatology, Rheumatology, Pulmonology, etc.> |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Time allotment |  |

* + 1. **Study Protocols for Clarificatory Interview (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Study Protocol Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Required expertise | <Pediatrics, Oncology, Dermatology, Rheumatology, Pulmonology, etc.> |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Time allotment |  |

* + 1. **Withdrawal of Study Protocol Applications (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Withdrawal Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Required expertise | <Pediatrics, Oncology, Dermatology, Rheumatology, Pulmonology, etc.> |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |

* + 1. **Study Protocol Amendment Applications (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Amendment Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Required expertise | <Pediatrics, Oncology, Dermatology, Rheumatology, Pulmonology, etc.> |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Time allotment |  |
| Remarks/Description |  |

* + 1. **Continuing Review Applications**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Required expertise | <Pediatrics, Oncology, Dermatology, Rheumatology, Pulmonology, etc.> |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Time allotment |  |
| Remarks/Description |  |

* + 1. **Final Reports**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Required expertise | <Pediatrics, Oncology, Dermatology, Rheumatology, Pulmonology, etc.> |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Time allotment |  |
| Remarks/Description |  |

* + 1. **Study Protocol Non-Compliance (Deviation or Violation) Reports: (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Required expertise | <Pediatrics, Oncology, Dermatology, Rheumatology, Pulmonology, etc.> |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Time allotment |  |
| Noncompliance report1: |  |
| Corrective Action Taken |  |
| Noncompliance report2: |  |
| Corrective Action Taken |  |
| Noncompliance report3: |  |
| Corrective Action Taken |  |

* + 1. **Early Study Termination Reports (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Required expertise | <Pediatrics, Oncology, Dermatology, Rheumatology, Pulmonology, etc.> |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Time allotment |  |
| Remarks/Description |  |

* + 1. **Queries, Notifications, and Complaints (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Required expertise | <Pediatrics, Oncology, Dermatology, Rheumatology, Pulmonology, etc.> |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Time allotment |  |
| Remarks/Description |  |

* + 1. **SAE and SUSAR Reports (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF |  |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| SAE Reviewer |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Time allotment |  |
| Remarks/Description |  |

* + 1. **Site Visit Reports: (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Site Visit Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Required expertise | <Pediatrics, Oncology, Dermatology, Rheumatology, Pulmonology, etc.> |
| Primary reviewers and site visit team |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Time allotment |  |
| Remarks/Description |  |

* 1. **REPORT OF PROTOCOL SUBMISSIONS CLASSIFIED AS EXEMPTED FROM ETHICAL REVIEW**
  2. **REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW AND FULL BOARD PROTOCOLS WITH MODIFICATION EXPEDITED AT THE LEVEL OF THE CHAIR**
  3. **REPORT OF RESULTS OF PROTOCOL SUBMISSIONS PROCESSED BY SJREB**

1. **Other Matters**
2. **Adjournment**

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

Chair, UPMREB Review Panel

**ANNEX 1**

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

1. **Exempted Protocols (NONE or #)**

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

**ANNEX 2**

**Report of Protocol Submissions for Expedited Review and Full Board Protocols with Modification Expedited at the Level of the Chair**

1. **Approved Protocols (NONE or #)**

|  |  |
| --- | --- |
| UPMREB 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 Protocol Amendment Applications (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Amendment Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Remarks/Description |  |
| **ACTION** |  |
| **Date of Action** |  |

1. **Continuing Review Applications (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Remarks/Description |  |
| **ACTION** |  |
| **Date of Action** |  |

1. **Final Reports (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Action taken | **Decision Points** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| **Date of Action** |  |

1. **Early Study Termination Reports (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Remarks/Description |  |
| **ACTION** |  |
| **Date of Action** |  |

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

|  |  |
| --- | --- |
| UPMREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Remarks/Description |  |
| **ACTION** |  |
| **Date of Action** |  |

**ANNEX 3**

**Report of results of protocol submissions processed by SJREB**

1. **Approved Protocols (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| SJREB Code |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |
| Study Protocol Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Country Pricipal Investigator |  |
| Site Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |

1. **Study Protocol Amendment Applications (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| SJREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Amendment Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Country Pricipal Investigator |  |
| Site Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Remarks/Description |  |
| **ACTION** |  |
| **Date of Action** |  |

1. **Continuing Review Applications (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| SJREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Country Pricipal Investigator |  |
| Site Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Remarks/Description |  |
| **ACTION** |  |
| **Date of Action** |  |

1. **Final Reports (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| SJREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Country Pricipal Investigator |  |
| Site Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Action taken | **Decision Points** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| **Date of Action** |  |

1. **Early Study Termination Reports (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| SJREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Country Pricipal Investigator |  |
| Site Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Remarks/Description |  |
| **ACTION** |  |
| **Date of Action** |  |

1. **Queries, Notifications, and Complaints (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| SJREB Code |  |
| Initial Approval Date | <dd/mm/yyyy> |
| Date of Last Continuing Review Approval | <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Version and date of latest approved protocol | <Version #> <dd/mm/yyyy> |
| Version and date of latest approved ICF | <Version #> <dd/mm/yyyy> |
| Report Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Country Pricipal Investigator |  |
| Site Principal Investigator |  |
| Type of review |  |
| Primary reviewers |  |
| Technical Review |  |
| Funding agency/CRO |  |
| Remarks/Description |  |
| **ACTION** |  |
| **Date of Action** |  |

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

Chair, UPMREB Review Panel