|  |
| --- |
| **Minutes of the NAME OF PANEL**  **<ordinal> REGULAR MEETING**  **<dd Month yyyy>, Venue, Time** |

**ATTENDANCE**

|  |  |
| --- | --- |
| **PRESENT** | **ABSENT** |
| (Name1, position, expertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)  (Name2, position, expertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)  (Name3, position, expertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)  (Name4, position, expertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)  (Name5, position, expertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)  (Name6, position, expertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)  (Name7, position, expertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)  Others:  Panel Staff | (Name1, position, expertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female)  (Name2, position, expertise, healthsci/non-healthsci, affiliated/non-affiliated, male/female) |

1. **CALL TO ORDER**

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

1. **DETERMINATION OF QUORUM**

A quorum was declared with the presence of **<#>** members, inclusive of the presence of **<#>** non-institutionaland **<#>** non-medical members, and as confirmed by the Panel Secretary, <Title, Name, Surname>.

1. **DISCLOSURE OF CONFLICT OF INTEREST**

<Title, Surname of Panel 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 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. **APPROVAL OF THE AGENDA OF THE MEETING**

<Title, Surname of Panel Chair>presided over the discussion of the agenda. The agenda were revised during the discussion and finalized.

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

<Title, Surname of Panel Chair>presided over the discussion of the minutes of the **(UPMREB Review Panel)** meeting held last <dd/mm/yyyy> (**Date of last meeting).** 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 UPMREB Panel action
2. **STUDY 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 |  | |
| Presence of required expertise | 1. <Type of expertise><Y/N> 2. <Type of expertise><Y/N>   (Example:   1. Pediatrics - Y 2. Pulmonologist - N | |
| Primary reviewers |  | |
| Technical Review |  | |
| Funding Agency/CRO |  | |
| Study site |  | |
| Quorum status |  | |
| Conflict of interest |  | |
| Assessment of scientific soundness | 1. **Social Value** 2. **Objectives/Expected output** 3. **Literature review** 4. **Research design** 5. **Sampling design, sample size** 6. **Inclusion criteria, exclusion criteria, withdrawal criteria** 7. **Data collection and processing plan** 8. **Specimen collection and processing** 9. **Statistical and data analysis plan** 10. **PI qualifications** 11. **Suitability and choice of site** 12. **Validation of research instruments among Filipino participants** 13. **Duration of participant involvement** | |
| Assessment of ethical issues | 1. **Conflict of Interest and Transparency:** 2. **Privacy and confidentiality including data protection plan** 3. **Vulnerability** 4. **Risks and safety monitoring plan** 5. **Benefits** 6. **Compensation** 7. **Community Considerations** 8. **Dissemination or data sharing plan** 9. **Documentation of collaborative study and TOR** | |
| Assessment of informed consent issues | 1. **Informed consent process and recruitment:** 2. **Informed Consent Form (ICF) (including translation)** | |
| Conclusion and recommendations |  | |
| Action taken | **Decision** (Approve <date of continuing review>, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the level of the Panel Chair, Disapprove, Pending, if major clarifications are required before a decision can be made) | |
| Approval expiration date (if applicable) |  |
| Frequency of continuing review (in case of approval |  |
| Reasons |  | |

* + 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 |  |
| Presence of required expertise | 1. <Type of expertise><Y/N> 2. <Type of expertise><Y/N>   (Example:   1. Pediatrics - Y 2. Pulmonologist - N |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Study site |  |
| Quorum status |  |
| Conflict of Interest |  |
| ***Assessment of PI response to initial review*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision** (Approve <date of continuing review>, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the level of the Panel Chair, Disapprove, Pending, if major clarifications are required before a decision can be made) |
| Approval expiration date (if applicable) |  |
| Frequency of continuing review (in case of approval |  |
| Reasons |  |

* + 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 |  |
| Presence of required expertise | 1. <Type of expertise><Y/N> 2. <Type of expertise><Y/N>   (Example:   1. Pediatrics - Y 2. Pulmonologist - N |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of PI responses to Panel queries*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision** (Decisions are based on the Panel’s assessment of the PI’s response to their queries.) |
| Reasons |  |

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

|  |  |
| --- | --- |
| UPMREB Code |  |
| Withdrawal Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Presence of required expertise | 1. <Type of expertise><Y/N> 2. <Type of expertise><Y/N>   (Example:   1. Pediatrics - Y 2. Pulmonologist - N |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of reasons for Study Protocol withdrawal*** |  |
| Conclusion and recommendations | 1. **Total of participants enrolled** 2. **Status of participants currently enrolled** 3. **Effect of withdrawal on safety and well-being of subjects** 4. **Effect on overall risk-benefit ratio** |
| Action taken | **Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| Reasons |  |

* + 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 |  |
| Presence of required expertise | 1. <Type of expertise><Y/N> 2. <Type of expertise><Y/N>   (Example:   1. Pediatrics - Y 2. Pulmonologist - N |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of amendment requested*** | **1. Effect of amendment on feasibility of the study**  **2. Effect of amendment on safety and well-being of subjects**  **3. Effect of amendment on overall risk-benefit ratio** |
| Conclusion and recommendations |  |
| Action taken | **Decision** (Approve, Minor modification to the study protocol amendment, citing reasons for action, subject to expedited review at the level of the Panel Chair, Major modification to the study protocol amendment, stating reasons for action, subject to full board review, Disapprove, Pending, if major clarifications are required before a decision can be made) |
| Reasons |  |

* + 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 |  |
| Presence of required expertise | 1. <Type of expertise><Y/N> 2. <Type of expertise><Y/N>   (Example:   1. Pediatrics - Y 2. Pulmonologist - N |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of progress reported*** | 1. **Protocol or conduct of the study** 2. **Changes in the participant population, recruitment or selection criteria since the last review/approval** 3. **Changes in the informed consent process or documentation since the last review/ approval** 4. **Any new information that might affect the panel’s evaluation of the risk/benefit assessment of human participants involved in this study protocol** 5. **New/additional investigational new drug/device registrations associated with this study new intervention(s) or methods in the conduct of study that is/are not in the approved protocol** 6. **Changes in the investigators and study personnel** 7. **Changes in collaborating sites/institutions** 8. **Others** 9. **Protection of welfare** 10. **Updates or measures in the protocol to guarantee protection of privacy and confidentiality of participant information in compliance with local regulations (e.g. Data privacy act of 2012)** 11. **Any unexpected discomforts, complications, or side effects noted or any safety issues** 12. **Participants that have withdrawn from this study since the last review/approval** 13. **Changes in conflict of interest** 14. **Management of biobank, as applicable** 15. **Site visit conducted for this study** 16. **Others** 17. **Assessment of progress status on overall risk-benefit assessment ratio** |
| Conclusion and recommendations |  |
| Action taken | **Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| Reasons |  |

* + 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> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Presence of required expertise | 1. <Type of expertise><Y/N> 2. <Type of expertise><Y/N>   (Example:   1. Pediatrics - Y 2. Pulmonologist - N |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of Final Report:*** |  |
| Conclusion and recommendations |  |
| Action taken | **Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| Reasons |  |
| <add more as needed> |  |

* + 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> |
| Date of Report | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Presence of required expertise | 1. <Type of expertise><Y/N> 2. <Type of expertise><Y/N>   (Example:   1. Pediatrics - Y 2. Pulmonologist - N |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of Non-Compliance Report:*** | 1. **Description of reported deviation** 2. **Nature of report** 3. **Description of investigator preventive action** 4. **Description of investigator corrective action** 5. **Investigator’s assessment on the impact of the deviation on the safety of participant/s** 6. **Investigator’s assessment on the impact of the deviation on the credibility of data** 7. **Description of sponsor corrective action** 8. **Over-all assessment, including whether noncompliance have potentially serious consequences that could critically affect data integrity or put patients’ safety at risk** |
| Conclusion and recommendations |  |
| Action taken | **Decision** (No further action required, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| Reasons |  |
| <add more as needed> |  |

* + 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> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Presence of required expertise | 1. <Type of expertise><Y/N> 2. <Type of expertise><Y/N>   (Example:   1. Pediatrics - Y 2. Pulmonologist - N |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of risks from early termination*** | 1. **Current participants being enrolled and might be affected** 2. **Summary of results to date** 3. **Reason for termination with justifications** 4. **Over-all assessment, including implication of the report on the rights, safety, and welfare of the study participants, including adapting specific provisions for continued protection and dissemination of specific information to the study participants** |
| Conclusion and recommendations |  |
| Action taken | **Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| Reasons |  |

* + 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> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Presence of required expertise | 1. <Type of expertise><Y/N> 2. <Type of expertise><Y/N>   (Example:   1. Pediatrics - Y 2. Pulmonologist - N |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of query:*** | 1. **Type of query** 2. **Effect of query on safety and well-being of subjects** 3. **Effect on overall risk-benefit ratio** |
| Conclusion and recommendations |  |
| Action taken | **Decision (**No further action, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| Reasons |  |
| ***Assessment of notification:*** | 1. **Type of notification** 2. **Effect of notification on safety and well-being of subjects** 3. **Effect on overall risk-benefit ratio** |
| Conclusion and recommendations |  |
| Action taken | **Decision (**No further action, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| Reasons |  |
| ***Assessment of complaint:*** | 1. **Type of complaint** 2. **Effect of complaint on safety and well-being of subjects** 3. **Effect on overall risk-benefit ratio** |
| Conclusion and recommendations |  |
| Action taken | **Decision (**No further action, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| Reasons |  |

* + 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: | <Version #> <dd/mm/yyyy> | |
| Report Date | <dd/mm/yyyy> | |
| Study Protocol Title |  | |
| Principal Investigator |  | |
| Type of Review |  | |
| SAE Reviewer |  | |
| Technical Review |  | |
| Funding Agency/CRO |  | |
| Quorum status |  | |
| Conflict of Interest: |  | |
| ***Assessment of reported SAE::*** | Suspected Drug |  |
| Patient no |  |
| Report Date |  |
| Date of SAE |  |
| Date of 1st use |  |
| Duration of Therapy |  |
| Age |  |
| Sex |  |
| Country |  |
| Nature of SAE | <Patient died, Involved or prolonged inpatient hospitalization, involved persistence or significant disability or incapacity, life threatening |
| Summary description of the SAE |  |
| Co-morbidities |  |
| Reaction abated after stopping drug | <Yes/No/NA> |
| Reaction appeared after reintroduction | <Yes/No/NA> |
| Treatment of SAE |  |
| Status |  |
| Country |  |
| Causality assessment | <Certain, Probable, Possible, Unlikely, Conditional, Unclassifiable> |
| Reason/Comment |  |
|  | Adequacy of Treatment of SAE |  |
| Conclusion and recommendations |  | |
| Action taken | **Decision Points** (No further action required, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) | |
| Reasons |  | |
| <add more as needed> |  | |

* + 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 |  |
| Presence of required expertise | 1. <Type of expertise><Y/N> 2. <Type of expertise><Y/N>   (Example:   1. Pediatrics - Y 2. Pulmonologist - N |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Quorum status |  |
| Conflict of Interest: |  |
| ***Assessment of Site Visit Report*** | 1. **Details on the site visit conducted (i.e. when, where, team composition, reason for site visit)** 2. **Overall assessment, including the implications of results of the Site Visit on the rights, safety, and welfare of the study participants; and overall determination of protocol compliance in the study site.** |
| Conclusion and recommendations |  |
| Action taken | **Decision Points (**No further action required, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| Reasons |  |

* 1. **REPORT OF PROTOCOL SUBMISSIONS CLASSIFIED AS EXEMPTED FROM ETHICAL REVIEW**
     1. **Protocols Exempted from Ethical Review (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 |  |
| Time allotment |  |
| Date of 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 (NONE or #)**

|  |  |
| --- | --- |
| UPMREB Code |  |
| Study Protocol Initial Submission Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Study Protocol Approval Date | <dd/mm/yyyy> |

* + 1. **Study Protocol Amendments (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> |
| Date of Amendment Submission | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Action taken | **Decision** (Approval, Minor modification to the study protocol amendment, citing reasons for action, subject to expedited review at the level of the Panel Chair, Major modification to the study protocol amendment, stating reasons for action, subject to full board review, Disapprove, Pending, if major clarifications are required before a decision can be made) |
| 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> |
| Date of Report | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Action taken | **Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| 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> |
| Date of Report | <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. **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> |
| Date of Report | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Action taken | **Decision** (No further action, 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> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Action taken | **Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| Date of Action |  |

* + 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> |
| Application Date | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Primary Reviewers |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Action taken | **Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| Date of Action |  |

* 1. **REPORT OF RESULTS OF PROTOCOL SUBMISSIONS PROCESSED BY SJREB**
     1. **Approved Protocols (NONE or #)**

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

* + 1. **Study Protocol Amendments (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> |
| Date of Amendment Submission | <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** (Approval, Minor modification to the study protocol amendment, citing reasons for action, subject to expedited review at the level of the Panel Chair, Major modification to the study protocol amendment, stating reasons for action, subject to full board review, Disapprove, Pending, if major clarifications are required before a decision can be made) |
| 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> |
| Date of Report | <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** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| 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> |
| Date of Report | <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. **Study Protocol Non-Compliance (Deviation or Violation) 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> |
| Date of Report | <dd/mm/yyyy> |
| Study Protocol Title |  |
| Principal Investigator |  |
| Type of Review |  |
| Country Pricipal Investigator |  |
| Site Principal Investigator |  |
| Technical Review |  |
| Funding Agency/CRO |  |
| Action taken | **Decision** (No further action, 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> |
| Application 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** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| 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> |
| Application 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** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made) |
| Date of Action |  |

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

Meeting was adjourned at **<time>.**

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