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| --- |
| UNIVERSITY OF SANTO TOMAS HOSPITALRESEARCH ETHICS COMMITTEE6th Floor St. John Macias O.P. BuildingA.H. Lacson St. Sampaloc, Manila 1015 PhilippinesTelephone: +63 2 8731-3001 local 2610 Email: *usth\_irb@yahoo.com.ph***UNIVERSITY OF SANTO TOMAS HOSPITAL**España Blvd., Manilalogo copy |

**MINUTES OF THE MEETING FORM**

**<ordinal> REGULAR MEETING**

**<DD/MM/YYYY>**

**Time, Venue**

**ATTENDANCE:**

**Present:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Name of Member** | **Initials** | **Designation** | **Expertise** |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |

**Also Present:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Name of Member** | **Initials** | **Designation** | **Expertise** |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |

**Absent:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Name of Member** | **Initials** | **Designation** | **Expertise** |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |

**AGENDA OF THE MEETING:**

1. **OPENING PRAYER**

1. **CALL TO ORDER**
2. **DECLARATION OF QUORUM**
3. **DISCLOSURE OF CONFLICT OF INTEREST**
4. **APPROVAL OF THE PROVISIONAL AGENDA**

|  |  |  |
| --- | --- | --- |
| **Type of Submissions** | **Full Board Review** | **Expedited Review** |
| New Protocol  |  |  |
| Resubmission |  |  |
| Amendments |  |  |
| SAEs |  |  |
| Deviation / Non Compliance |  |  |
| Continuing Review |  |  |
| Site Visit |  |  |
| Final Report |  |  |
| Early Termination  |  |  |
| **Total:**  |  |  |

1. **REVIEW & APPROVAL OF THE MINUTES OF THE PREVIOUS MEETING (Date)**
2. **BUSINESS ARISING FROM THE MINUTES OF THE MEETING**
3. **NEW BUSINESS**
4. **FULL REVIEW OF PROPOSALS:**
	1. **NEW PROTOCOLS FOR INITIAL FULL REVIEW**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **REC-YYYY/MM/NNN/LL**  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department |  |
| Sponsor |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted |  |
| Discussion/Comments: | 1. **In Protocol:**
2. Scientific Soundness
3. Technical Soundness
4. Ethical Soundness
5. Social Value
6. Vulnerability issue
7. Measures to protect vulnerability population
8. Risk/benefit ratio
9. Measures to mitigate risks
10. Confidentiality and privacy
11. Informed Consent process, form and content
12. **In Informed Consent Forms:**
 |
| Recommendations: |  |
| Decision: |  |
| Decision letter date |  |

* 1. **PROTOCOLS FOR CLARIFICATORY INTERVIEW**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **REC-YYYY/MM/NNN/LL**  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department |  |
| Sponsor |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| Recommendations: |  |
| Decision: |  |
| Decision letter date |  |

* 1. **RESUBMITTED PROTOCOLS FOR FULL REVIEW**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **REC-YYYY/MM/NNN/LL**  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department |  |
| Sponsor |  |
| Type of review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted |  |
| Recommendations: |  |
| Decision: |  |
| Decision letter date |  |

* 1. **PROGRESS REPORTS FOR FULL REVIEW**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **REC-YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| USTH-REC Approval Date |  |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Review |  |
| Primary Reviewers |  |
| Documents Submitted: |  |
| Recommendations: |  |
| Decision: |  |
| Decision letter date |  |

* 1. **PROTOCOL AMENDMENT FOR FULL REVIEW**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **REC-YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| USTH-REC Approval Date |  |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Review |  |
| Primary Reviewers |  |
| Documents Submitted: |  |
| Recommendations: |  |
| Decision: |  |
| Decision letter date |  |

* 1. **PROTOCOL DEVIATION & VIOLATIONS REPORT FOR FULL REVIEW**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **REC-YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Review |  |
| Primary Reviewers |  |
| Documents Submitted: |  |
| Recommendations: |  |
| Decision: |  |
| Decision letter date |  |

* 1. **SAE and SUSAR REPORTS FOR FULL REVIEW**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **REC-YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| ***Assessment of SAEs reported*** |  |
| SAE 1 | Submission Date |  |
| Date of SAE |  |
| Subject No. Age/Sex |  |
| Country |  |
| Nature of AE |  |
| Report No. |  |
| Recommendations: |  |
| Decision: |  |
| Decision letter date |  |

* 1. **CONTINUING REVIEW APPLICATIONS FOR FULL REVIEW**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **REC-YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| USTH-REC Approval Date |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| Recommendations: |  |
| Decision: |  |
| Decision letter date |  |

* 1. **FINAL REPORTS FOR FULL REVIEW**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **REC-YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| Summary of Results |

|  |  |
| --- | --- |
| No. of study participants in the beginning of the study: |  |
| No. of participants at the end of the study:  |  |
| Duration of the study (inclusive dates:  |  |
| Initial Recruitment Date: |  |
| End of Recruitment Date: |  |

 |
| Conclusion |  |
| Recommendations: |  |
| Decision: |  |
| Decision letter date |  |

* 1. **EARLY TERMINATION REPORTS FOR FULL REVIEW**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **REC-YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| Recommendations: |  |
| Decision: |  |
| Decision letter date |  |

* 1. **SITE VISIT REPORTS FOR FULL BOARD REVIEW**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **REC-YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| Recommendations: |  |
| Decision: |  |
| Decision letter date |  |

* 1. **QUERIES OR COMPLAINTS**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **REC-YYYY/MM/NNN/LL**  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Details of queries/ complaints |  |
| Recommendations: |  |
| Decision: |  |
| Decision letter date |  |

1. **REPORT ON EXPEDITED REVIEW OF PROPOSALS**
	1. **NEW PROTOCOLS FOR EXPEDITED REVIEW:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.**  | **USTH-REC Prot. Ref. No** | **Protocol No./Title** | **Principal Investigator** | **Primary Reviewers** | **Status** |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |

* 1. **RESUBMITTED PROTOCOLS FOR EXPEDITED REVIEW**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.**  | **USTH-REC Prot. Ref. No** | **Protocol No./Title** | **Principal Investigator** | **Primary Reviewers** | **Status** |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |

* 1. **PROTOCOL AMENDMENT APPLICATION FOR EXPEDITED REVIEW**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.**  | **USTH-REC Prot. Ref. No** | **Protocol No./Title** | **Principal Investigator** | **Primary Reviewers** | **Status** |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |

* 1. **CONTINUING REVIEW APPLICATION FOR EXPEDITED REVIEW**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.**  | **USTH-REC Prot. Ref. No** | **Protocol No./Title** | **Principal Investigator** | **Primary Reviewers** | **Status** |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |

* 1. **FINAL REPORTS FOR EXPEDITED REVIEW**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.**  | **USTH-REC Prot. Ref. No** | **Protocol No./Title** | **Principal Investigator** | **Primary Reviewers** | **Status** |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |

1. **PROTOCOLS FOR EXEMPT REVIEW**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **REC-YYYY/MM/NNN/LL**  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| Comments and Recommendations |  |
| Decision: |  |
| Decision letter date |  |

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

**Minutes of the meeting prepared by:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SIGNATURE OVER PRINTED NAME**

REC Office Secretary

**Reviewed by:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SIGNATURE OVER PRINTED NAME**

REC Member Secretary

**Noted by:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SIGNATURE OVER PRINTED NAME**

REC Head