**PROVISIONAL AGENDA FORM**

**<ordinal> REGULAR MEETING**

**<DD/MM/YYYY>**

**Time, Venue**

 **AGENDA OF THE MEETING:**

1. **OPENING PRAYER**
2. **CALL TO ORDER**
3. **DECLARATION OF QUORUM**
4. **APPROVAL OF THE PROVISIONAL AGENDA**
5. **DISCLOSURE OF CONFLICT OF INTEREST**
6. **REVIEW & APPROVAL OF THE MINUTES OF THE PREVIOUS MEETING (Date)**
7. **BUSINESS ARISING FROM THE MINUTES OF THE MEETING**
8. **NEW BUSINESS**
9. **FULL REVIEW OF PROPOSALS:**
	1. **NEW PROTOCOLS FOR INITIAL FULL REVIEW:**

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

* 1. **PROTOCOLS FOR CLARIFICATORY INTERVIEW:**

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

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

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

* 1. **PROTOCOL AMENDMENTS FOR FULL REVIEW:**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Research |  |
| Type of Review |  |
| Primary Reviewers |  |
| Documents Submitted: |  |
| Summary & Reasons for Amendment |

|  |  |  |
| --- | --- | --- |
| **Current REC Approved Protocol** | **Proposed Amendments:** | **Reason/Justification****for the Amendments:** |
|  |  |  |
|  |  |  |

 |

* 1. **PROTOCOL DEVIATION & VIOLATION REPORTS FOR FULL REVIEW:**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Research |  |
| Type of Review |  |
| Primary Reviewers |  |
| Documents Submitted: |  |
| Study Updates | 1. Start of study:
2. Expected end of study:
3. Number of required participants:
4. Number of enrolled participants:
5. Number of participants who withdrew:
 |
| Details of Protocol Deviation  | 1. Description of Reported Deviation/Violation
2. Nature of Deviation/Violation
3. Impact of deviation/violation on participants’ risks/harms and integrity of data
4. Investigator’s assessment on impact of deviation on credibility of data:
5. Description of investigators corrective action and preventive action (CAPA):
6. Sponsor assessment of severity:
7. Description of Sponsor corrective action:
8. Actions taken to prevent future deviation/violation:
 |

* 1. **CONTINUING REVIEW APPLICATIONS & PROGRESS REPORTS FOR FULL REVIEW:**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| USTH-REC Approval Date |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Research |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| Study Updates | 1. Start of study:
2. Expected end of study:
3. Number of required participants:
4. Number of enrolled participants:
5. Number of participants who withdrew:
6. Deviations from the approved protocol:
7. New information (literature or in the conduct of the study) that may significantly change the risk-benefit ratio:
8. Issues/problems encountered:
9. Progress Status (short description and indicate completion status, e.g., 50% complete, 75% complete):
10. Justification for application for Continuing Review:
 |

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

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Research |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| Study Updates | 1. Start of study:
2. End of study:
3. Number of required participants:
4. Number of enrolled participants:
5. Number of participants who withdrew:
6. Deviations from the approved protocol:
7. Issues/problems encountered:
 |
| Summary of Results & Conclusion | 1. Results:
2. Conclusions:
3. Actions for dissemination of study results:
 |

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

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Research |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| Study Updates | 1. Start of study:
2. Expected end of study:
3. Number of required participants:
4. Number of enrolled participants:
5. Number of participants who withdrew:
 |
| Details of Early Termination | 1. Reason/s for cancellation/termination:
2. Support mechanisms/interventions for enrolled participants
3. Post-termination actions:
 |

* 1. **SAE & SUSARS SAFETY REPORTS FOR FULL REVIEW:**

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| --- | --- |
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Research |  |
| 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. |  |

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

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Research |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| Study Updates | 1. Start of study:
2. Expected end of study:
3. Number of required participants:
4. Number of enrolled participants:
5. Number of participants who withdrew:
6. Deviations from the approved protocol:
7. Onsite SAE reports:
 |
| SAE/Pharmacovigilance Team Report: | 1. Date & Time of Visit:
2. Reasons for site visit:
3. Name of REC Representatives
4. Study Team present during visit:
5. Findings:
 |

* 1. **QUERIES OR COMPLAINTS:**

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

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

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

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

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

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

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor |  |
| Type of Research |  |
| Type of Review |  |
| Primary Reviewers |  |
| Documents Submitted: |  |
| Summary & Reasons for Amendment |

|  |  |  |
| --- | --- | --- |
| **Current REC Approved Protocol** | **Proposed Amendments:** | **Reason/Justification****for the Amendments:** |
|  |  |  |
|  |  |  |

 |
| Recommendations: |  |
| Decision  |  |
| Decision Letter Date |  |

* 1. **PROTOCOL DEVIATION/ NON-COMPLIANCE & VIOLATION REPORTS FOR EXPEDITED REVIEW:**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor |  |
| Type of Research |  |
| Type of Review |  |
| Primary Reviewers |  |
| Documents Submitted: |  |
| Study Updates | 1. Start of study:
2. Expected end of study:
3. Number of required participants:
4. Number of enrolled participants:
5. Number of participants who withdrew:
 |
| Details of Protocol Deviation  | 1. Description of Reported Deviation/Violation
2. Nature of Deviation/Violation
3. Impact of deviation/violation on participants’ risks/harms and integrity of data
4. Investigator’s assessment on impact of deviation on credibility of data:
5. Description of investigators corrective action and preventive action (CAPA):
6. Sponsor assessment of severity:
7. Description of Sponsor corrective action:
8. Actions taken to prevent future deviation/violation:
 |
| Recommendations: |  |
| Decision |  |
| Decision Letter Date |  |

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

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| USTH-REC Approval Date |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor |  |
| Type of Research |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| Study Updates | 1. Start of study:
2. Expected end of study:
3. Number of required participants:
4. Number of enrolled participants:
5. Number of participants who withdrew:
6. Deviations from the approved protocol:
7. New information (literature or in the conduct of the study) that may significantly change the risk-benefit ratio:
8. Issues/problems encountered:
9. Progress Status (short description and indicate completion status, e.g., 50% complete, 75% complete):
10. Justification for application for Continuing Review:
 |
| Recommendations: |  |
| Decision |  |
| Decision Letter Date |  |

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

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor |  |
| Type of Research |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| Study Updates | 1. Start of study:
2. End of study:
3. Number of required participants:
4. Number of enrolled participants:
5. Number of participants who withdrew:
6. Deviations from the approved protocol:
7. Issues/problems encountered:
 |
| Summary of Results & Conclusion | 1. Results:
2. Conclusions:
3. Actions for dissemination of study results:
 |
| Recommendations: |  |
| Decision  | **☐** | Approved |
| **☐** | Request information |
| **☐** | Recommend further action |
| Decision Letter Date |  |

* 1. **CANCELLED PROTOCOLS REPORT:**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL**  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor/CRO |  |
| Type of Research |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| Study Updates | 1. Start of study:
2. Expected end of study:
3. Number of required participants:
4. Number of enrolled participants:
5. Number of participants who withdrew:
 |
| Details of Cancellation | 1. Reason/s for cancellation/termination:
2. Support mechanisms/interventions for enrolled participants
3. Post-termination actions:
 |
| Recommendations: |  |
| Decision  | **☐** | Approval of the decision |
| **☐** | Request for additional information |
| **☐** | Require further action |
| Decision Letter Date |  |

1. **PROTOCOLS EXEMPT FROM REVIEW:**
	1. **NEW PROTOCOLS EXEMPT FROM REVIEW:**

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

1. **FINAL REPORT PROTOCOLS EXEMPT FROM REVIEW:**

|  |  |
| --- | --- |
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL**  |
| REC Initial Approval Date |  |
| Submission Date | < Date\_Month\_Year > |
| Protocol No./Title |  |
| Principal Investigator |  |
| Department  |  |
| Sponsor |  |
| Type of Research |  |
| Type of Review |  |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: |  |
| Study Updates | 1. Start of study:
2. End of study:
3. Number of required participants:
4. Number of enrolled participants:
5. Number of participants who withdrew:
6. Deviations from the approved protocol:
7. Issues/problems encountered:
 |
| Summary of Results & Conclusion | 1. Results:
2. Conclusions:
3. Actions for dissemination of study results:
 |
| Recommendations: |  |
| Decision  | **☐** | Approved |
| **☐** | Request information |
| **☐** | Recommend further action |
| Decision Letter Date |  |

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

**Agenda 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