1. **LEVEL OF ACCREDITATION APPLIED FOR:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Please check:** |  [ ]  Level 1 | [ ] Level 2 | [ ] Level 3 |

1. **INFORMATION ABOUT THE RESEARCH ETHICS COMMITTEE:**

|  |  |
| --- | --- |
| **Name of the REC:** | Click here to enter text. |
| **Name of Institution:** | Click here to enter text. |
| **Address: (No., Street, Town/City, Province, Region)** | Click here to enter text. |
| **REC Tel. No.:** | Click here to enter text. | **REC Email address:** | Click here to enter text. |
| **Name of Chairperson:** | Click here to enter text. |
| **Telephone:** | Click here to enter text. | **Mobile:** | Click here to enter text. |
| **Email address:** | Click here to enter text. |
| **Contact Person:** | Click here to enter text. | **Position:** | Click here to enter text. |
| **Contact Person Mobile No.:** | Click here to enter text. | **Contact Person Email address:** | Click here to enter text. |
| **Date of Administrative Issuance that established the REC, its Independence in Decision-making and Statement of Administrative Support (Please attach copy of document):** | Click here to enter text. |
| **Date of Administrative Issuance regarding Policy on Requirement for Ethics Review of Research involving Human Participants (Please attach copy):** | Click here to enter text. |
| **Frequency of REC meetings:** | [ ]  Once a month | [ ]  Once every 3 months |
| [ ]  Once every 2 months | [ ]  Specify \_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. **REC CATEGORY ACCORDING TO PHREB ACCREDITATION POLICIES & REQUIREMENTS**

|  |
| --- |
|[ ]  Academic Institution REC (AI-REC) |
|[ ]  Hospital REC (H-REC) |
|[ ]  Government Agency REC (G-REC) |
|[ ]  Regional Health Research and Development Consortium REC (RHRDC REC)  |
|[ ]  Cluster REC (C-REC) |
|[ ]  Research Site REC (R-REC) |
|[ ]  Others (*Please describe*)Click here to enter text. |

1. **COMPOSITION OF REC:**

| **NAME\*** | **PROFESSION/****SPECIALTY / OCCUPATION***(e.g. Natural Science, Physical Science, Social Science, Law, Theology, Arts, Humanities, Medical Specialty)* | **SEX** | **AGE CATEGORY** | **AFFILIATED WITH INSTITUTION** | **HIGHEST EDUCATIONAL ATTAINMENT** *(e.g., Doctoral, Masters, Bachelor’s Degree, etc.)* *Note: Please attach CV* | **ROLE IN THE REC***(e.g. Medical/ Scientist, Non-Scientist)* | **DATE OF APPOINTMENT AND TENURE***Note: Please attach appointment document* | **ETHICS TRAINING***(e.g. Basic, GRP, GCP, SOP, Advance)* *Note: Please attach latest certificate of training* |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **M** | **F** | **≤50** | **>50** | **YES** | **NO** |  |  |  |  |
| **Chair:**Click here to enter text. |  |[ ] [ ] [ ] [ ] [ ] [ ]  Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Vice-Chair:**Click here to enter text. | Click here to enter text. |[ ] [ ] [ ] [ ] [ ] [ ]  Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Secretary:**Click here to enter text. | Click here to enter text. |[ ] [ ] [ ] [ ] [ ] [ ]  Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Members:** | Click here to enter text. |[ ] [ ] [ ] [ ] [ ] [ ]  Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
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| 1. Click here to enter text.
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|  | **TOTAL** | **0** | **0** | **0** | **0** | **0** | **0** |

***\*Add rows when needed***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name of Staff Secretary** | **Birth Year** | **Sex** | **Date of Appointment** **(attach appointment document)** | **Educational Background** | **Part-time/Full-time** | **Assignments aside from REC work** |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

1. **TYPES OF RESEARCH REVIEWED: *(\*Please attach PHREB Form 1.3 - Protocol Summary)***

|  |  |
| --- | --- |
| **Type of research** | **Number of Protocols Reviewed in the two (2) years** **prior to the current year** |
| **Year 1**Jan to Dec <insert year> | **Year 2**Jan to Dec <insert year> | **Current Year**Jan to <insert month> <insert year> |
| Social/behavioral research includes KAPs of communities, impact of public health interventions | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Public health research includes epidemiologic researches (prevalence, surveys, incidence) | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Biomedical studies include preventive, retrospective, prospective and diagnostic studies, and use of human material and data | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Health operations research includes studies on health programs and policies | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Clinical trials (sponsored) |  |  |  |
| * Phase 1
 | 0 | 0 | 0 |
| * Phase 2
 | 0 | 0 | 0 |
| * Phase 3
 | 0 | 0 | 0 |
| * Phase 4
 | 0 | 0 | 0 |
| Clinical trials (researcher-initiated) |  |  |  |
| Others (Please specify) Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Total no. of Protocols Reviewed** | **0** | **0** | **0** |

1. **MANUAL OF STANDARD OPERATING PROCEDURES:**

**Does the REC have a written Manual of Standard Operating Procedures? YES** [ ]  **NO** [ ]

 **Date when the SOP was approved:** Click here to enter a date.

|  |
| --- |
| **List of REC Standard Operating Procedures (please check if available):** |
|[ ]  1. Table of Contents
 |[ ]  n. Three (3) Protocol File Folders (for Level 2)* One (1) Completed Full Review
* One (1) On-going Full Review
* One (1) Completed Expedited Review
 |
|[ ]  1. Overview/Introduction (Mission-Vision of the Institution, institutional organizational chart that includes the REC, institutional policies related to human protection & research ethics review, structure & mandate of REC)
 |[ ]  o. Review of the Final Report |
|  |  |[ ]  p. Review of an Early Termination Report |
|  |  |[ ]  q. Management of Appeals |
|  |  |[ ]  r. Conduct of Site Visits |
|[ ]  1. REC Structure & Composition (Selection and Appointment of Members)
 |[ ]  s. Preparing for a Meeting |
|[ ]  1. Designation of Officers
 |[ ]  t. Preparing the Meeting Agenda |
|[ ]  1. Appointment of Independent Consultants
 |[ ]  u. Conduct of Meeting |
|[ ]  1. Expedited Review
 |[ ]  v. Preparing the Minutes of Meeting |
|[ ]  1. Full Review
 |[ ]  w. Communicating REC Decisions |
|[ ]  1. Management of Initial Submission
 |[ ]  x. Management of Incoming and Outgoing Communications |
|[ ]  1. Review of Resubmissions
 |[ ]  1. Management of Active Files
 |
|[ ]  1. Review of Progress Reports
 |[ ]  1. Archiving
 |
|[ ]  1. Review of Protocol Deviation and Violation
 |[ ]  1. Management of Access to Confidential Files
 |
|[ ]  1. Review of Safety Reports (SAEs, SUSARS, RNEs)
 |[ ]  1. Management of Queries and Complaints
 |
|[ ]  1. Management of an Application for Continuing Review
 |[ ]  1. Writing and Revising SOPs
 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Submitted by:** | Click here to enter text.Signature over Printed Name | **Date of Application:** | Click here to enter a date. |
| **Noted by:** | Click here to enter text.Signature over Printed Name of REC Chair | **Date:** | Click here to enter a date. |
| **Endorsed by:** | Click here to enter text.Signature over Printed Name of Head of Institution | **Date:** | Click here to enter a date. |