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. | 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. |
|  | **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. |