

**Application for Ethics Review of a New Protocol \* (Form 2.1)**

***Instructions to the PI/Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked below (in Section 3. Checklist of Documents).***

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| 1. **General Information** | | | | | | | | | | | | |
| \*Title of Study | |  | | | | | | | | | | |
| \*IRB Code  (To be provided by IRB) | | |  | | | | | \*Study Site | |  | | |
| \*Name of PI/Researcher) | | |  | | | | | Contact Information | | \*Tel No: | | |
| \*Mobile No: | | |
| \*Co-researcher (if any) | | |  | | | | | \*Fax No: | | |
| \*Email: | | |
| \*Institution | | |  | | | | | | | | | |
| \*Address of Institution | | |  | | | | | | | | | |
| \*Type of Study | | Clinical Trial (Sponsored)  Clinical Trials (Researcher-initiated)  Health Operations Research (Health Programs and Policies)  Social / Behavioral Research  Public Health / Epidemiologic Research | | | | | | Biomedical research (Retrospective, Prospective and diagnostic studies)  Stem Cell Research  Genetic Research  Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | |
| Multicenter  (International) | | | | Multicenter (National) | | | | | | Single Site |
| \*Source of Funding | | Self-funded  Government-Funded  Scholarship/Research Grant | | | | | | | Sponsored by a Pharmaceutical Company  Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Institution-Funded | | | |
| Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | |
| \*Duration of the study | Start date: | | |  | | | | No. of study participants: | |  | | |
| End date: | | |  | | | |
| \*Has the Research undergone Technical Review? | | | | | | | Yes (please attach technical review results)  No | | | | | |
| \*Has the Research been submitted to another IRB? | | | | | | | Yes  No | | | | | |
| 1. **Brief Description of the study** | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| 1. **Checklist of Documents** | | | | | | | | | | | | |
| **Basic requirements:**  Letter request for review  Endorsement/Referral Letter  Full proposal / study protocol  Technical Review Approval  Curriculum Vitae of PI/Researcher/s  Informed Consent Form  English version  Filipino version  Hiligaynon version  Assent Form (if applicable)  English version  Filipino version  Hiligaynon | | | | | | | | **Supplementary Documents:**  Questionnaire (if applicable)  Data Collection Forms (if applicable)  Product Brochure (if applicable)  Philippine FDA Marketing Authorization or Import License (if applicable)  Permit/s for special populations (please specify)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Others (please specify)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| **Accomplish**  **\_­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Signature  **Date submitted** \_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | |
| **---------------------- To be filled by the IRB Staff ----------------------** | | | | | | | | | | | | |
| **Completeness of Document** | | | | | **Complete**  **Incomplete** | | | | | |  | |
| **Remarks** | | | | |  | | | | | |
| **Date Received:** | | | | |  | | | | | |
| **Received by:** | | | | |  | | | | | |