

 **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**
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|  |
| 1. **Checklist of Documents**
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| **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:** |  |