**APPLICATION FORM FOR PROTOCOL REVIEW**

| **DATE SUBMITTED:** | **DD / MMMM/ YYYY** | **FIERC PROTOCOL CODE** |  |
| --- | --- | --- | --- |

| **TYPE OF SUBMISSION** | **□ INITIAL REVIEW** | **□ RESUBMISSION** | **□ AMENDMENT** |
| --- | --- | --- | --- |

| **PROTOCOL TITLE:** |  |
| --- | --- |

| **PRINCIPAL INVESTIGATOR:** |  | **TEL. NO.:** |  |
| --- | --- | --- | --- |
| **MOBILE NO:** |  |
| **EMAIL:** |  |

| **CO-INVESTIGATOR/S** (IF ANY) |  |
| --- | --- |

| **NAME OF INSTITUTION** |  | **DIVISION** (FOR FNRI EMPLOYEES) |  |
| --- | --- | --- | --- |

| **INSTITUTION ADDRESS** |  |
| --- | --- |

| **TYPE OF STUDY** | **□** Clinical Trial *(Sponsored)***□** Clinical Trials *(Researcher-Initiated)***□** Health Operations Research  *(Health Programs and Policies)***□** Social and Behavioral Research**□** Public Health or Epidemiologic | **□** Biomedical Research*(Retrospective, Prospective and Diagnostic Studies***□** Stem Cell Research**□** Genetic Research**□** Internet Research**□** Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| --- | --- | --- |
| **□** Multicenter *(International)* | **□** Multicenter *(National)* | **□** Single Site |

| **SOURCE OF FUNDING** | **□** Self-Funded**□** Government-Funded**□** Scholarship / Research Grant**□** Institution-Funded | **□** Sponsored by Pharmaceutical  Company, Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**□** Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **DURATION OF THE STUDY** | **START DATE:** | **NUMBER OF STUDY PARTICIPANTS** |  |
| --- | --- | --- | --- |
| **END DATE:** |

| **HAS THE RESEARCH UNDERGONE TECHNICAL REVIEW *(For Initial Submission Only)*** | **□** YES *(please attach DOST-FNRI TECCOM 002)* | **□ NO**  |
| --- | --- | --- |

| **HAS THE RESEARCH BEEN SUBMITTED TO ANOTHER RESEARCH ETHICS COMMITTEE** | **□ YES** | **□ NO**  |
| --- | --- | --- |
| **CHECKLIST OF DOCUMENTS FOR SUBMISSION** |
| **BASIC REQUIREMENTS: (INITIAL SUBMISSION)****□** Letter request for review**□** Endorsement / Referral Letter**□** Foreign / Local Institutional Ethics Review  Approval *(if applicable)***□** Form 03-01 v.2 Application Form For Protocol Review**□** Form 03-02 v.2 Protocol Evaluation Form**□** Form 03-03 v.2 Informed Consent Evaluation Form**□** Form 03-04 v.2 Protocol Summary Sheet**□** Full Proposal / Study Protocol**□** Informed Consent Form **□** English version **□** Filipino version **□** Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**□** Assent Form *(if applicable)* **□** English version **□** Filipino version **□** Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**□** Curriculum Vitae of the Principal Investigator and  Project Team Members**□** Good Clinical Practice Training Certificate *(For Clinical Trial)* ***/*** Ethics Training Certificate (e.g. BRET, GRP and others) of Principal Investigator and Study Team Members**□** Confidentiality Agreement & Disclosure of Conflict of Interest for Researchers**◻** FNRI TECCOM 002 Form **SUPPLEMENTARY DOCUMENTS** *(if applicable)***□ Questionnaire****□ Data Collection Tools****□ Product Brochure****□ Material Transfer Agreement** *(e.g. for human*  *tissue samples sent to other countries)***□ Permit(s) for special populations**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****□ Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **FOR RESUBMISSION & AMENDED PROTOCOL:****If changes were made on the Protocol / ICF:*** Highlight the changes made

**BASIC REQUIREMENTS:****□** Letter request for review including a summary of the revisions made on the protocol and the list of documents submitted**□** Form \_\_\_\_\_\_\_\_ Review of Resubmitted Protocol Form**□** Form \_\_\_\_\_\_\_\_ Protocol Amendment Review Form**□** Soft copy of Protocol and other documents attached  |
| **ACCOMPLISHED BY:****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** ***(Signature over printed name)******Date: dd / mmmm/yyyy)*** |
| **TO BE FILLED OUT BY THE REC SECRETARIAT** |
| **COMPLETENESS OF DOCUMENT** | **□ Complete** **□ Incomplete** | *(Please stamp here)* |
| **REMARKS** |  |
| **DATE RECEIVED:** |  |
| **RECEIVED BY:** |  |