**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:** |  | | |