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| **APPLICATION FOR INITIAL REVIEW**  **To be filled by Investigator** | | | | | | | | | | | | | | | | | | |
| **Sponsor Protocol**  **Number:** | | |  | | | | | **IRB Protocol**  **Number:** | | | | | | | | |  | |
| **Submission Date:** | | |  | | | | | | | | | | | | | | | |
| **Protocol Title:** | | |  | | | | | | | | | | | | | | | |
| **Principal Investigator:** | | |  | | | | | | | | | | | | | | | |
| **Telephone number:** | | |  | | | | | **Fax** | | | | | | | | |  | |
| **E-mail:** | | |  | | | | | **Preferred Contact** | | | | | | | | |  | |
| **Institute:** | | |  | | | | |  | | | | | | | | |  | |
| **Investigator Initiated:** | | | * **Yes** | | | * **No** | |  | | | | | | | | |  | |
| **Sponsor Initiated** | | | * **Yes** | | | * **No** | | **Name of Sponsor** | | | | | | | | |  | |
| **(Relationship with sponsor)** | | | | | | | | | | | | | | | | | | |
| **Are you a regular employee of the sponsor?**  **Did you do consultancy or part time work for the sponsor?**  **In the past year, did you receive > P250,000 or from the sponsor?**  **Other ties with the sponsor? If Yes pls Specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | * **Yes** | | | | | * **No** |
| * **Yes** | | | | | * **No** |
| * **Yes** | | | | | * **No** |
| * **Yes** | | | | | * **No** |
| ***No Conflict of Interest Declaration by Principal Investigator:***  **I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Investigator.** | | | | | | | | | | | | | | | | | | |
| **PI Signature:** | | |  | | | | | | | | | | | | | | | |
| **Name of Adviser/Mentor** | | |  | | | | | | | | | | | | | | | |
| **Documents submitted: (Please Check)** | | | | | | | | | | | | | | | | | | |
| **REQUIRED FOR ALL INITIAL SUBMISSIONS** | | | | | | | | **OPTIONAL: only IF APPLICABLE TO PROTOCOL** | | | | | | | | | | |
| * Protocol * Protocol summary (for clinical trials) * Informed consent form (when in use) * Research Team List * CVs & Research Ethics training Certificates * Study budget | | | | | | | | * Technical Review Certificate (for PI Initiated) * Questionnaire * Case report forms (CRF) * Investigator brochure (for Clinical Trials) * GCP certificates (for Clinical Trials) * Advertisement | | | | | | | | | | |
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| **ARE THE DOCUMENTS SUBMITTED COMPLETE:** | | | | | | | | | * **YES** | | | | | * **NO** | | | | |
| **DO NOT ACCEPT INCOMPLETE PACKAGES** | | | | | | | | | | | | | | | | | | |
| **Type of Research/Phase of Trial** | | | | | | | | | | | | | | | | | | |
| * Survey * Screening * Clinical trial * Genetic * Single Center | | * Social * Observational * Phase I * Retrospective * Multicenter | | | | * Medical * Epidemiologic * Phase II * Prospective * Others \_\_\_\_\_ | | | | * Community * Interventional * Phase III * Others\_\_\_\_ | | | | | | * Individual Based * Phase IV | | |
|  | | | | | | | | | | | | | | | | | | |
| **Study Duration:** |  | | | **Received By:** | | |  | | | | | **Date:** | | |  | | | |
| **Assigned Primary Reviewer\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | | | | | | |
| **Exempt** | | | | | **Expedited** | | | | | | * **Full Board** | | | | | | | |
| * Protocols that neither involves human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) * Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the IRB for exemption from review:   + Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;   + Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:   + There will be no disclosure of the human participants’ responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation;   + The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant. * Protocols that involve the use of publicly available data or information. | | | | | * Minimal risk protocols * Chart review * Survey of non-sensitive nature * Use of anonymous or anonymized laboratory/pathology samples or stored tissues or data | | | | | | * Protocols that entails more than minimal Risk * Protocols involving Vulnerable populations, particularly prisoners * Sensitive topics, including illegal behaviors * Research involving genetic testing * A complex research design requiring the expertise of multiple board members to evaluate | | | | | | | |
| **Type of Review: ⬜ Exempt ⬜ Expedited ⬜ Full Board** | | | | | | | | | | | | | | | | | | |
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| **IRB Chair/Member Secretary Name & Signature** | | | | | | | | | | | | | | | **DATE** | | | |