|  |
| --- |
| **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
 |
|  |
| **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** |
|  |
| **IRB Chair/Member Secretary Name & Signature** | **DATE** |