**PELI-IRB PROTOCOL SUBMISSION CHECKLIST**

**IRB Protocol Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

| **SUBMISSION DATE** |  |
| --- | --- |
| **SPONSOR PROTOCOL NUMBER** |  |
| **STUDY PROTOCOL TITLE** |  |
| **PRINCIPAL INVESTIGATOR** |  |
| **TELEPHONE NUMBER** |  |
| **EMAIL ADDRESS** |  |
| **INSTITUTE** |  |
| **SPONSOR** |  |
| **TYPE OF SUBMISSION** | **☐** Initial **☐** Resubmission |
| **STUDY DETAILS** | Type of Research: Clinical Trial / Social Science others:  Phase: 1 2 3 4  Study Duration: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **STATEMENT OF AGREEMENT WITH ETHICAL PRINCIPLES IN RELEVANT GUIDLINES** | By writing my initials in this section, I am expressing my agreement and compliance with the ethical principles set out in relevant research ethics guidelines, including but not limited to, the ICH-GCP, Declaration of Helsinki 2008.  Primary Investigator’s Initials: \_\_\_\_\_\_\_\_\_\_\_\_ |
| **PI SIGNATURE** |  |

**Below is the following list of documents to be submitted at least 4 weeks prior to Third Week of Months of January, April, July and December full board meeting:**

Kindly check all submitted documents attached to this form

**☐**Completely filled out **Form 2.2.1**, **Form 2.2.2,** **Form 2.3, Form 2.4**

**☐** Completely filled out **Form 2.10** (for Off-sites with which the study is to be conducted outside PELI)

**☐**Protocol Package (Three hard copies and an electronic copy)

Please ensure that the following are given importance in the protocol package:

* + - A description of the process used to obtain and document consent
    - A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants,
    - A description of the arrangement for indemnity, if applicable
    - A description of arrangements for insurance coverage for research participants
    - A statement of agreement to comply with ethical principles set out in relevant guidelines

**☐**Protocol

**☐**Protocol Summary

**☐**Investigator’s brochure

**☐**Informed consent form

* + - English
    - Filipino
    - Chinese language (as needed)

**☐**Assent form (if applicable)

* + - English
    - Filipino
    - Chinese language (as needed)

**☐**Declaration of conflict of interest

**☐**Terms of reference / Clinical Trial Agreement

\*Note: Non-disclosure/concealment of specific study budget allocation may be allowed for purposes of confidentiality between site and sponsor.

**☐**Data collection form/s or case report forms

**☐**CV of the PI and co-investigators and the GCP certificate (as necessary but mandatory for sponsor-initiated studies), updated, signed and dated

**☐**GANTT chart (as necessary)

**☐**Clearance or permit from other regulatory agencies (e.g. FDA approval, Non-significant Risk (NSR)/Significant Risk (SR) rating for new IND and Medical Devices)

**☐**Ads for recruitment, if applicable

**☐**Insurance Policy, if applicable

**☐**All significant previous decisions by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere)

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Received by: Date: