PROTOCOL REVIEW CHECKLIST

To the Principal Investigator:

Please be advised that IEC receives <u>complete</u> proposal submission packages only between the <u>1st and the 15th day of each month</u> to ensure consideration at the following month's meeting. The cut-off period will not be extended under any circumstance.

You are requested to obtain an electronic copy of this Form, fill-out the requested information, and make your submission both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

STUDY PROTOCOL INFORMATION		
Protocol Submission Date		<dd/mm/yy>
Title		Version Number, Date
Principal Investigator (PI)	(Title, Name. Surname>	
PI Address		Tel No. Cell No. Email
Sponsor/CRO		
Study Site		
Type of Submission		☐ Initial Review ☐ Continuing Review of Approved Protocols
Mode of submission asd		☐ Post ☐ E submission ☐ in Person
Documents submitted asd		☐ Complete ☐ Incomplete; will submit on……..
Received By:	Name Signature Date:	

I. MANDATORY COMPONENTS	Version/ Date	Remarks
☐ Cover Letter		
☐ Accomplished Review Checklist **(DLSHSI-IEC FORM 2(A) V1-2012)**		
☐ Review Application Form **(DLSHSI-IEC FORM 2(B) V1-2012)**		
☐ Study Protocol (*10 copies, complete with relevant documents)*		
☐ Informed Consent Form (*for studies involving human participants*) ☐ English version ☐ Tagalog , and/or other Local Version(s) *N.B. Must have Version No, Date, Page No. in the footer*		
☐ Parent's Consent Form (*for studies involving children/minors and relevant populations*) ☐ English version ☐ Tagalog , and/or other Local Version(s) *N.B. Must have Version No, Date, Page No. in the footer*		
☐ Assent Form (*from children cognitively capable of giving consent*) ☐ English version ☐ Tagalog , and/or other Local Version(s) *N.B. Must have Version No, Date, Page No. in the footer*		
☐ Pharmacogenetic /Pharmacogenomic ICF (as needed by the study) *N.B. Must have Version No, Date, Page No. in the footer*		
☐ Data Collection Forms (*specify*)		
☐ Updated CV of PI and study team members **(DLSHSI-IEC FORM 2(D) V1-2012)**		
☐ Proof of GCP Training in the last 3 years (*for those doing clinical studies*)		
☐ Ethical and/or Technical Approval from other Ethics/Technical Review Committee(s)		
☐ Institutional Endorsement (from the VC, Dean, or Medical Director)		
☐ Regulatory clearances (FDA approval for Phase I,II, II, IV clinical trials)		
☐ **Electronic copy of :** ☐ Review Checklist ☐ Review Application Form		

☐ Study Protocol ☐ Informed Consent Assessment Form (*for studies involving human participants*) ☐ English version ☐ Tagalog , and/or other Local Version(s) ☐ Parent's Consent Form, Assent Form (*for studies involving children/minors and relevant populations*) ☐ English version ☐ Tagalog , and/or other Local Version(s) ☐ Assent Form (*from children cognitively capable of giving consent*) ☐ English version ☐ Tagalog , and/or other Local Version(s) ☐ Pharmacogenetics ICF		
II. OTHER REQUIRED DOCUMENTS (*depending on the particular study/project application being submitted*		
☐ Investigator's Brochure (*for clinical trials phase I, II, III*); Basic Product Information Document (*for clinical trials phase IV*)		
☐ CRFs		
☐ Recruitment advertisements (*as needed by the study*)		
☐ Other information/ documents for participants (*such as diaries, etc*., questionnaire)		
☐ Site Resources Checklist (*for clinical Trials*)		
☐ Memorandum of Agreement (*for collaborative studies*)		
☐ Details of Funding Agency/Sponsor		
☐ Institutional Biosafety Committee Approval (*for studies involving hazardous biological materials*)		
☐ Material Transfer Agreement (*for studies involving transfer of biological specimens*)		
☐ National Commission for Indigenous People (NCIP) Clearance (*for studies with indigenous populations*)		
☐ Insurance/Indemnity Policy		
☐ Others (*specify*)		

I understand that this Application for IEC Review and Approval will NOT be accepted unless all necessary documents are submitted.

I declare the authenticity of the documents submitted with this Application.

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Signature Over Printed Name of Principal Investigator *Date*