



INSTITUTIONAL ETHICS AND REVIEW BOARD
12th Floor, Our Mother of Perpetual Succour Medical Specialty Center
Perpetual Succour Hospital
Gorordo Avenue, Cebu City
Tel No/Fax No: +63-32-342-0853

<h1 style="margin: 0;">Initial Submission Checklist</h1>	PSH-IERB Form 2B
--	-----------------------------

PSH-IERB Code:	Date Submitted:
Protocol Number: Protocol Title:	
Sponsor:	Sponsor's Local Address:
Principal Investigator:	Sub-Investigator:
	Study Coordinator:
Email address:	Contact No.:

No. of Copies required	Document to be Submitted:	No. of Copies submitted
2	a. Letter of Intent addressed to the Chairperson with itemized list of documents submitted in protocol package	
1	b. Proof of payment of review fee	
2	c. Application for Protocol Review Form (Form 2A)	
2	d. Initial Submission Checklist (Form 2B)	
For expedited review: 2 copies	e. Protocol Package including the ff: i. Clinical Study Protocol ii. Informed Consent Form in at least 2 languages (English and Cebuano)	
For full board review: 12 copies or 3 hard copies provided soft copy is available	iii. Investigator's Brochure	
	f. Curriculum Vitae of the Principal Investigator	
	g. GCP Training Certificate of PI	
	h. Conflict of Interest Statement Form of the PI (Form 2C)	
	i. Contracts and approval of relevant offices (Memorandum of Agreement if study is collaborative in nature; Materials Transfer Agreement, Intellectual Property Approval, Investigational Device Exemption, when relevant)	
	j. Description of the arrangements for indemnity (WHO 5.3.13), and the arrangements for insurance; if applicable.	
2	k. Previous decisions by other regulatory authorities on the proposed study, if applicable, such as: i. Results of technical/ethical review from other Ethics committees ii. Approval Letter from Department Research Committee for Residents'/Fellows' studies	
2	l. Authorization from Chief Executive Officer if accessing medical records	

Submitted by: _____

Date: _____

Signature over Printed Name