



INSTITUTIONAL ETHICS AND REVIEW BOARD
12th Floor, Our Mother of Perpetual Succour Medical Specialty Center
Perpetual Succour Hospital
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Review of Amendments

PSH-IERB
Form 4B

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

Date of Initial Approval:
Documents to be Amended: please specify _____
<i>(Highlight the changes made)</i>
Note: (Attach two copies of the amended documents together with the Letter of Intent. Include summary of the revisions made on the protocol and the list of documents submitted)
Classification of Amendments: <input type="radio"/> Major Amendment <input type="radio"/> Minor Amendment

Submitted by: <i>SIGNATURE OVER PRINTED NAME</i>	DATE:
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For IERB members: Please write your comments below and indicate decision. State the reason and action required to continue the study.

1. Is there a change in the risks? Comments:	<input type="radio"/> Yes	<input type="radio"/> No
2. Is there a change in the benefits? Comments:	<input type="radio"/> Yes	<input type="radio"/> No
3. Is there a change in the risk to benefit ratio? Comments:	<input type="radio"/> Yes	<input type="radio"/> No
4. Is there a need to revise the ICF? Comments:	<input type="radio"/> Yes	<input type="radio"/> No
5. Is there a need to reconsent study participants? Comments:	<input type="radio"/> Yes	<input type="radio"/> No
6. Is the amendment major?	<input type="radio"/> Yes	<input type="radio"/> No
Recommendation: <input type="checkbox"/> Approved <input type="checkbox"/> Modification required (pls. specify): _____ _____ <input type="checkbox"/> Disapprove (pls. explain) _____ _____ _____ Reviewer's signature over printed name Date reviewed: _____		