PHILIPPINE HEART CENTER
Institutional Ethics Review Board
8/F Medical Arts Building
East Avenue, Quezon City, 1100 Philippines
Tel./Fax no. 9252401 loc.3899; email add: irbphc@gmail.com

Deviation/Violation/Non-compliance Report Form

I. General Information:

IERB no.	DETR no.	Protocol no.	
Project Title:			
Protocol Version no. and Date		Phone Number:	
Person Completing Form:			
Name of Principal Investigator (PI):		Research Site:	
Patient ID#	Age:	Gender: ☐ Male ☐ Female	
Protocol violation identified by: ☐ PI ☐ Coordinator ☐ Monitor ☐ Other: _____			

II. Reporting Criteria:

This deviation/violation adversely affects: *(check all that apply)*

YES	NO	
[ ]	[ ]	rights/welfare of subject(s)
[ ]	[ ]	safety of subject(s)
[ ]	[ ]	integrity of research data
[ ]	[ ]	subject's willingness to continue study participation

(Note: if you have checked "NO" to all of the above, please do not proceed with this report. This is not a reportable deviation/violation. However, if the IRB has specifically requested that you submit this report because of a lapse in approval or late submission, all sections of this form must be completed.)

III. Characterization:

The deviation/violation involves:

[ ] Enrollment process *(inclusion/exclusion criteria, ascertainment/recruitment, etc.)*
[ ] Consent process *(oral or written)*
[ ] Drug/Device Administration *(dosage, schedule, route of administration, formulation, etc.)*
[ ] Other Protocol Activities (*research activities, data analysis, reporting, etc.)*
[ ] Complaint from research subject
[ ] Audit finding that requires corrective action
[ ] Other:

III. **Description:**

1. Date(s) of the deviation/violation:

Note: If more than 14 business days prior to the date of submission to the IRB (or more than 7 days for an unanticipated study-related death), please explain the delay in reporting.

2. Please describe in detail the specific deviation/violation:

3. If the purpose of this deviation report is a lapse in IRB approval, please describe all study activities, including enrollment, interventions, data analysis, that have occurred during the lapse:

4. Please explain how/why the deviation/violation occurred:

5. Please describe how the deviation/violation affected the:
   (i) risk/benefit ratio for the subject(s):

   (ii) integrity of the research data:

   (iii) subject's willingness to continue study participation:

6. Does this protocol deviation/violation require revision of the protocol and/or consent form?

[ ] Yes *(if yes, please submit a completed Amendment form and revised documents with changes marked)*
[ ] No

7. Please describe: (i) corrective actions, if applicable, for the deviation/violation; and (ii) a plan for preventing the recurrence of the deviation/violation: _____

By signing below, I declare that the above is an accurate and complete description of the protocol deviation/violation and that, upon receipt of the IRB's review, I will fully and immediately implement any corrective actions required by the IRB.

_____ _____
Signature of PI Date

For IERB Use Only

IERB Chairman/Designee Review of Problem Report:

I have reviewed this reported protocol deviation/violation and determined that: *(check all that apply)*

[ ] No further action is required.
[ ] PI must complete the Prompt Reporting
[ ] The corrective action described in this form below is acceptable. PI must issue a statement to the IERB that he/she has implemented the corrective action plan as described.
[ ] PI must submit an interim report to the IERB on _____ describing his/her progress in implementing the corrective action described below.
[ ] The attached corrective actions must be implemented.
[ ] The deviation/violation reported appears to represent serious or continuing non-compliance. Review according to that policy is required.
[ ] Other: _____

_____ _____
Signature of IERB Chair/Designee **Date**