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|  | **HOLY ANGEL UNIVERSITY**  **Institutional Review Board**  4th floor, San Francisco de Javier Building  1 Holy Angel Avenue, Santo Rosario, Angeles City 2009  *Telephone*: +63 45 8888691 local 1540 ; *Email*: irb@hau.edu.ph |

**PROTOCOL DEVIATION/VIOLATION REPORT FORM**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Protocol No.:** | | | | | |
| **Study Protocol Title:** | | | | | |
| **Initial Approval Date:** | | | | | |
| **Principal Investigator:** | | | | | |
| **E-mail:** | | | **Telephone:** | | **Mobile:** |
| **Study Site:** | | | | | |
| **Study Site Address:** | | | | | |
| **Sponsor:** | | | | | |
| **Sponsor Contact Person:** | | | | | |
| **E-mail:** | | | **Telephone:** | | **Mobile:** |
| **No. of Events:** | | | | | |
| **No. Of Onsite Events:** | | | | | |
| **Report Number** | **Event Number** | **Event** | | | |
| <Report Number>  <Date of Report> | <Event Number> | **Deviations from the approved protocol** | |  | |
|  |  | **Explanation for deviation/violation** | |  | |
|  |  | **Impact of deviation/violation on participants’ risks/harms and integrity of data** | |  | |
|  |  | **Causality Assessment of Sponsor** | |  | |
|  |  | **Action** | |  | |
|  |  | **Outcome** | |  | |
| **Signature of Principal Investigator:** | | | | | |
| **Date of Submission:** | | | | | |

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| **Comments and Recommendations of Reviewer:** | |
| Risk/benefit Assessment |  |
| Effect on the safety, well-being and rights of the participants |  |
| **RECOMMENDATION**   * SUBMISSION OF ADDITIONAL INFORMATION * INVITATION TO A CLARIFICATORY INTERVIEW * SUBMISSION OF CORRECTIVE ACTION * REQUIREMENT FOR AN AMENDMENT * SITE VISIT * SUSPENSION OF RECRUITMENT * WITHDRAWAL OF ETHICAL CLEARANCE | |

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| **REVIEWER** |  | Signature |  |
| Date: |  | Name |  |
| **CHAIR** |  | Signature |  |
| Date: |  | Name |  |