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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 |

**REPORTABLE NEGATIVE EVENTS FORM**

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| **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:** |
| **Ethical Clearance Effectivity Period:** | | | |
| **RNE Report** | | | |
| **1. Start of Study:** | | **2. Expected end of study:** | |
| **3. Number of enrolled participants:** | | **4. Number of required participants:** | |
| **5. Description of Negative (harms, risks) Events**  **a. Involving Participants**  **b. Involving members of the Study Team**  **c. Involving Data safety and integrity** | | **6. Actions taken to prevent future RNEs, interventions and Outcomes** | |
| **Signature of Principal Investigator:** | | | |
| **Date of Submission:** | | | |

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| **Comments and Recommendations of Reviewer:** |
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| **Recommended Action:** *(for HAU-IRB use only)*   * NOTED WITH NO FURTHER ACTION REQUIRED * RECOMMEND SUSPENSION OF THE STUDY UNTIL RISK IS RESOLVED * WITHDRAWAL OF ETHICAL CLEARANCE * SUBMISSION OF A PLAN TO MITIGATE RISK/HARM * REQUIRE AN AMENDMENT TO THE PROTOCOL |

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