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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 |

**SERIOUS ADVERSE EVENTS 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> | | **Nature** | |  |
| **Date** | |  |
| **Age** | |  |
| **Sex** | |  |
| **Country** | |  |
|  |  | | **Co-morbidities** | |  |
|  |  | | **Causality Assessment of Investigator** | |  |
|  |  | | **Causality Assessment of Sponsor** | |  |
|  |  | | **Action** | |  |
|  |  | | **Outcome** | |  |
| **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 * FURTHER INFORMATION OR ACTION REQUIRED * SUSPENSION OF RECRUITMENT |

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