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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 ASSESSMENT FORM**

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| *To be filled up by the Secretariat* | |
| **HAU-Institutional Review Board**  Address:  1 Holy Angel Avenue, Santo Rosario, Angeles City 2009, Philippines | REFERENCE NO: |
| PROTOCOL NO:  PROTOCOL TITLE: | DATE PROTOCOL RECEIVED BY THE IRB: |
| *To be filled up by the Principal Investigator* | |
| Principal Investigator’s Signature over Printed Name:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  INSTITUTION:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ADDRESS: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | SPONSOR: |

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| **Primary Reviewer:** *(To be filled up by the Reviewer)* | | **🞏**  Scientist  **🞏** Non-Scientist |
| **RESEARCH PROTOCOL REQUIREMENTS**  *(to be filled out by the primary investigator)* | | **REVIEWER’S COMMENTS**  *(To be filled up by Reviewers)* |
| 1. Title of the study |  |  |
| 1. Investigators/researchers |  |  |
| 1. Significance of the study |  |  |
| 1. Literature review   *(may use separate sheet for literature review)* |  |  |
| 1. Objectives of the study |  |  |
| 1. Methodology and procedures |  |  |
| 1. Description of the study population |  |  |
| 1. Exclusion/Inclusion Criteria |  |  |
| 1. Ethical Considerations that should state what relevant international and national guidelines will be used as reference in the study and include ethical issues | |  |
| 1. Anticipated risks (how these will be minimized) and why they are outweighed by potential benefit |  |  |
| 1. Protection of confidentiality of data and privacy of the research participants |  |  |
| 1. Vulnerability of the research participants |  |  |
| 1. Management of adverse events |  |  |
| 1. How informed consent will be obtained |  |  |
| 1. Other potential conflicts of interest |  |  |
| 1. Statement of freedom to withdraw at any time without undue consequences |  |  |
| 1. Information regarding compensation for the   study participants/  subjects |  |  |
| 11. Data Analysis |  |  |
| 12. Safety Information | |  |
| 1. Safety Precaution |  |  |
| 1. Contact person and telephone number in case of emergency situation |  |  |

**OVERALL EVALUATION OF THE PROTOCOL:**

**CERTIFICATION:**

This is to certify that the above research protocol was

reviewed by:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Member Signature over Printed Name

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_

APPROVED

MINOR MODIFICATIONS

MAJOR MODIFICATIONS

DISAPPROVED

Details: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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