|  |  |
| --- | --- |
|  | **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 |

**AMENDMENT REVIEW FORM**

Any amendment to an approved protocol must be reviewed and approved by the IRB beforethe amendment is implemented. Such amendments could include changes to the study design, procedures, enrollment, methods of recruitment, personnel, funding source or the consent form/information sheet. This includes changes that appear to reduce risks to subjects. There are NO EXCEPTIONS to this rule.

Protocol #: \_\_\_\_\_\_\_\_\_\_\_\_\_

Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PI, Student Investigator, Correspondent Information:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Principal Investigator (PI)** | **Student Investigator** (only for Student Initiated Research) | **Correspondent** (primary point of contact for correspondence, if applicable) |
| Name (First, Last, Degree): |  |  |  |
| Department: |  |  |  |
| Mailing Address |  |  |  |
| Preferred Phone #: |  |  |  |
| Emergency Phone # (Required Full Board, More than Min. Risk only): |  |  |  |
| Preferred E-Mail Address: |  |  |  |

1. Describe *each* proposed amendment(s) and explain ***why*** it is being made.

|  |  |
| --- | --- |
| Propose amendment | Reason/Justification |
|  |  |

1. For *each* amendment listed above, explain whether the proposed amendment increases or decreases the level risk to participants (thereby changing the risk/benefit ratio) and, if so, describe. If the level of risk remains the same, describe this as well.

|  |  |  |
| --- | --- | --- |
| Propose amendment | Level of risk to participants *(increases, decreases, remains the same)* | Reason/Justification |
|  |  |  |

**Please answer the following questions:**

Has the funding source or the status of funding changed since initial or last re-approval review?

\_\_\_ Yes or \_\_\_ No

If yes, please amend the documents accordingly and, if a new funding source was added, please provide the IRB with a complete copy of the grant for review.

Does the study have a Certificate of Confidentiality? \_\_\_ Yes or \_\_\_ No

|  |  |
| --- | --- |
|  |  |
| **Original Signature of Principal Investigator** | **Date** |

|  |  |
| --- | --- |
|  |  |
| **Original Signature of Student Investigator**  **(Only for Student-Initiated Research)** | **Date** |

|  |  |
| --- | --- |
| **Comments of Reviewer:** | |
| Risk/benefit Assessment |  |
| Effect on the safety, well-being and rights of the participants |  |
| **RECOMMENDATION**   * APPROVED * REQUIRE ADDITIONAL INFORMATION: *(indicate information)* * RECONSENT REQUIRED * DISAPPROVED | |

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