**PALAWAN STATE UNIVERSITY**

**RESEARCH ETHICS REVIEW COMMITTEE**

Door 2, 1st Floor Student Innovation Park Building, PSU Main Campus

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US DOHHS-OHRP Registration No.: IRB00014070

PHREB Accreditation No.: L1-2023-058-01

**REPORTABLE NEGATIVE EVENT REPORT**

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR/LEAD RESEARCHER:**

All events perceived as negative in the conduct of the study should be reported here.

**PROTOCOL GENERAL INFORMATION**

|  |  |
| --- | --- |
| **PSURERC Code** |  |
| **Protocol Title** |  |
| **Principal Investigator/Lead Researcher** |  |
| **Protocol Approval Date/s** *(indicate dates of continuing review and/or protocol amendment dates, if applicable***)** |  |
| **Start Date** *(stated in the approved protocol; start of study includes the start of all data collection-related activities post-approval, e.g., communication with recruitment party, invitation, etc.; if not started, indicate target date; if started, indicate actual start date )* |  |
| **Target Completion Date** *(as stated in the approved protocol)* |  |
| **Study Site** |  |
| **Current Status** (*specify the current stage of the study)* |  |

**REPORTABLE NEGATIVE EVENT DETAILS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **What is involved** | **Description (including date, time, and location)** | **Impact on Participants, Data Integrity, and Researchers** | **Actions Taken** | **Planned Actions to be Taken to Avoid Future RNEs** | **Remarks of the Reviewer** (to be filled out by the reviewer) |
| Participants |  |  |  |  |  |
| Research Team |  |  |  |  |  |
| Data Integrity |  |  |  |  |  |
| Others |  |  |  |  |  |

**Principal Investigator/Lead Researcher: <Name and Signature>**

**Date of Report Submission: <Date>**

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*To be filled out by PSURERC Primary Reviewer*

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| --- | --- |
| **RECOMMENDATIONS:** | [ ] Request further action:<indicate action>  [ ] Pending: <indicate reason>  [ ] Suspend the study  [ ] Terminate the study  [ ] Withdraw approval |
| **Primary Reviewer** | *<Name and Signature>* |
| **Date of Recommendation** | *<Date>* |