PALAWAN STATE UNIVERSITY

U N IVER SIT Y R E SE AR C H ET H IC S R EVIE W C OM M IT T EE

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US DOHHS-OHRP Registration No.: IRB00014070

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

**EARLY STUDY TERMINATION APPLICATION/REPORT**

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: This form is required to apply for premature termination or suspension of a study and refers to ICH-GCP Section 4.12: PREMATURE TERMINATION OR SUSPENSION OF A TRIAL (applicable to clinical trials). Indicate NA if not applicable. Date and sign this form before submission. Approval of this application would require further completion of a Final Report.

GENERAL INFORMATION

|  |  |
| --- | --- |
| **PSURERC Code** |  |
| **Protocol Title** |  |
| **Principal Investigator/Lead Researcher** |  |
| **Type of Initial Review** |  |
| **Protocol Approval Date/s** *(indicate dates of continuing review and/or protocol amendment dates, if applicable***)** |  |
| **Target Start Date** *(as 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. )* |  |
| **Target Completion Date** *(as stated in the approved protocol)* |  |
| **Study Site** |  |

EARLY TERMINATION DETAILS

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| **1. STUDY ACTUAL START DATE:** <complete date> |
| **2. STUDY ACTUAL TERMINATION DATE :** <complete date the study was terminated> |
| **2. PROPOSED TERMINATION DATE:** <complete target date> |
| **3. PARTICIPANTS ENROLLED TO DATE:** |
| **4. SUMMARY OF RESULTS TO DATE:** |
| **5. REASON FOR TERMINATION with JUSTIFICATION:** |
| **6. SUPPORT MECHANISMS/INTERVENTIONS FOR ENROLLED PARTICIPANTS:** |
| **7. POST-TERMINATION ACTION PLANS** |
| **SIGNATURE OF PI:** |
| **DATE OF SUBMISSION OF APPLICATION/REPORT:** <complete date> |

**RECOMMENDATIONS (to be filled out by the Primary reviewer)**

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| **Comments of Primary Reviewer** |
| **RECOMMENDED ACTION:**   * APPROVE * REQUEST ADDITIONAL INFORMATION: (specify) * REQUEST FURTHER ACTION: (specify) * PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE * WITHDRAW APPROVAL |
| **Primary Reviewer: <Name and Signature> Date of Recommednation: <Date>** |