

|                                                                                   |                                                                       |  |                    |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------|--|--------------------|
|  | Pampanga State University Research Ethics Committee                   |  |                    |
|                                                                                   | <h2 style="text-align: center;">Reportable Negative Event Report</h2> |  |                    |
|                                                                                   |                                                                       |  | PSUREC Form No: 17 |
|                                                                                   |                                                                       |  | Version No: 1      |
|                                                                                   |                                                                       |  | Approval Date:     |
|                                                                                   | Effective Date:                                                       |  |                    |

## PSUREC Form 13-01: Reportable Negative Event Reportable

*Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents supporting the report below.*

| General Information              |  |                     |                |
|----------------------------------|--|---------------------|----------------|
| Title of the study               |  |                     |                |
| Version number/ date             |  |                     |                |
| REC Code (To be provided by REC) |  | Study Site          |                |
| <b>SJREB Code</b>                |  |                     |                |
| Project Leader                   |  | Contact Information | Tel/Mobile No. |
| Co-researcher (if any)           |  |                     | Email:         |
| Institution                      |  |                     |                |
| College                          |  | Department          |                |
| Address of Institution           |  |                     |                |

| To be filled up by Researcher                 |  |                                                                  |  |
|-----------------------------------------------|--|------------------------------------------------------------------|--|
| Reportable Negative Event Report              |  |                                                                  |  |
| Start of study                                |  | Expected end of study                                            |  |
| Number of enrolled participants               |  | Number of required participants (as approved)                    |  |
| Description of Negative (harms, risks) Events |  | Actions taken to prevent future RNEs, interventions and outcomes |  |
| a. Involving Participants                     |  |                                                                  |  |
| b. Involving members of the Study Team        |  |                                                                  |  |

|                                                                                   |                                                                   |                    |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------|--------------------|
|  | Pampanga State University Research Ethics Committee               |                    |
|                                                                                   | <h2 style="color: #4F81BD;">Reportable Negative Event Report</h2> | PSUREC Form No: 17 |
|                                                                                   |                                                                   | Version No: 1      |
|                                                                                   |                                                                   | Approval Date:     |
|                                                                                   |                                                                   | Effective Date:    |

|                                        |  |
|----------------------------------------|--|
| c. Involving Data safety and integrity |  |
|----------------------------------------|--|

|                         |  |
|-------------------------|--|
| Signature of Researcher |  |
| Name of the Researcher  |  |
| Date Submitted          |  |

| To be filled by the Staff |  |
|---------------------------|--|
| Date Received             |  |
| Received by               |  |

**To be filled by the Primary Reviewer**

**REC Members Recommendation**

**Decision**

- ☐ Noted, no further action  
☐ Request further information, specify \_\_\_\_\_  
☐ Request further action, specify \_\_\_\_\_
- *recommend suspension of the study until risk is resolved (suspension of enrolment and research procedures, but monitoring should be continued)*
  - *withdrawal of ethical clearance*
  - *submission of a risk mitigation plan*
  - *require an amendment to the protocol*

**Name of Primary Reviewer**

**Date**



Pampanga State University Research Ethics Committee

Reportable Negative Event Report

PSUREC Form No: 17

Version No: 1

Approval Date:

Effective Date:

Signature