**Reportable Negative Event (RNE) Report**

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *Obtain an electronic copy of this form and encode all information required in the space provided. Multiple deviations/violations classified under ONE type of review (expedited or full review) can be submitted in one form. Print the report in A4 size paper; then date and sign this form before submission.*

| UPLB REB CODE: |
| --- |
| STUDY PROTOCOL TITLE: |
| APPROVAL DATE: |
| PRINCIPAL INVESTIGATOR: |
| Email: | Telephone: | Mobile: |
| STUDY SITE: |
| STUDY SITE ADDRESS: |
| SPONSOR: |
| SPONSOR CONTACT PERSON: |
| Email: | Telephone: | Mobile: |
| REPORT SUBMISSION DATE: (to be filled out by UPLB REB) <dd/mm/yyyy> |
| **REPORTABLE NEGATIVE EVENT (RNE)**  |
| 1. START OF STUDY:
 | 1. EXPECTED END OF STUDY:
 |
| 1. NUMBER OF ENROLLED PARTICIPANTS:
 | 1. NUMBER OF REQUIRED PARTICIPANTS:
 |
| 1. NATURE OF NEGATIVE (HARMS, RISKS) EVENT:
	1. ⬜ INVOLVING PARTICIPANTS
	2. ⬜ INVOLVING MEMBERS OF THE STUDY TEAM
	3. ⬜ INVOLVING DATA SAFETY AND INTEGRITY
 |
| 1. DESCRIPTION OF NEGATIVE (HARMS, RISKS) EVENT:
 |
| 1. ACTIONS TAKEN TO PREVENT FUTURE RNES, INTERVENTIONS AND OUTCOMES:
 |
| DATE OF REPORTABLE NEGATIVE EVENT: <dd/mm/yyyy> |
| REPORTED BY: |
| DATE OF REPORT: <dd/mm/yyyy> |
| PI SIGNATURE: |

RECOMMENDATIONS (for UPLB REB use only)

| Comments of Primary Reviewer  |
| --- |
| RECOMMENDED ACTION:* NO FURTHER ACTION
* REQUEST INFORMATION: (indicate information)
* RECOMMEND FURTHER ACTION: (indicate action)
* PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE
 |
| PRIMARY REVIEWER |  | Signature  |  |
| Date: <dd/mm/yyyy> |  | Name | <Title, Name, Surname> |