**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 | | | |
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| 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> |