Study Protocol Noncompliance (Deviation or Violation) Report

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *This form refers to the requirements in ICH-GCP Sections 4.5: COMPLIANCE WITH PROTOCOL and 5.20: NONCOMPLIANCE. 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> |
| 1. NATURE OF REPORT
	1. ⬜ MINOR PROTOCOL DEVIATION (*nonsystematic* *protocol noncompliance with minor consequences, in terms of its effect on the participant’s/subject’s rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature*)
	2. ⬜ MAJOR PROTOCOL DEVIATION OR PROTOCOL VIOLATION *(persistent* *protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients’ safety at risk)*
 |
| 1. DESCRIPTION OF REPORTED DEVIATION/VIOLATION:
 |
| 1. DESCRIPTION OF INVESTIGATOR CORRECTIVE ACTION:
 |
| 1. SPONSOR ASSESSMENT OF SEVERITY:
	1. ⬜ MAJOR
	2. ⬜ MINOR
 |
| 1. DESCRIPTION OF SPONSOR CORRECTIVE ACTION:
 |
| DATE OF DEVIATION/VIOLATION: <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> |