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 | | | |
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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> |