S**TUDY PROTOCOL DEVIATION OR VIOLATION REPORT**

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *Obtain an electronic copy of this form and encode all information required in the space provided. Print the report in A4 size paper; then date and sign this form before submission.*

|  |  |  |
| --- | --- | --- |
| CLHRDC-ERC Code: | | |
| Study Protocol Title: | | |
| Principal Investigator: | | |
| Study Protocol Approval Date: <mm/dd/yyyy> | | |
| E-mail: | Telephone: | Mobile: |
| Report Submission Date: (to be filled out by CLHRDC-ERC) <mm/dd/yyyy> | | |
| 1. Description of reported deviation/violation (Identify who committed the deviation and describe the reported deviation):    1.  Patient: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    2.  Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 1. Nature of Report    1.  MINOR PROTOCOL DEVIATION (nonsystematic protocol noncompliance with minor consequences, in terms of its effect on the participant’s rights, safety of 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 integrity or put patients’ safety at risk) | | |
| 1. Description of investigator preventive action: | | |
| 1. Description of investigator corrective action: | | |
| Date of Deviation/Violation: <mm/dd/yyyy> | | |
| Reported by: | | |
| Date of report: <mm/dd/yyyy> | | |
| PI signature: | | |

RECOMMENDATIONS (for CLHRDC-ERC use only)

|  |
| --- |
| COMMENTS OF PRIMARY REVIEWER (i.e. whether noncompliance have potentially serious consequences that could critically affect data integrity or put patients’ safety at risk) |
| RECOMMENDED ACTION:   * NO FURTHER ACTION * REQUEST INFORMATION: (specify) * RECOMMEND FURTHER ACTION: (specify) * PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE |
| PRIMARY REVIEWER Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: <mm/dd/yyyy> Name <Title, Name, Surname> |