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.*

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| 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
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| 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)
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| 1. Description of investigator preventive action:
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| 1. Description of investigator corrective action:
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| Date of Deviation/Violation: <mm/dd/yyyy> |
| Reported by: |
| Date of report: <mm/dd/yyyy> |
| PI signature: |

RECOMMENDATIONS (for CLHRDC-ERC use only)

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| 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
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| PRIMARY REVIEWER Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: <mm/dd/yyyy> Name <Title, Name, Surname> |