**PROTOCOL DEVIATION AND VIOLATION REPORT**

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| **FIERC PROTOCOL CODE** | Click or tap here to enter text. | **APPROVAL DATE** | Click or tap to enter a date. |

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| **PROTOCOL TITLE** | Click or tap here to enter text. |

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| **PRINCIPAL INVESTIGATOR** | Click or tap here to enter text. | **INSTITUTION / DIVISION** | Click or tap here to enter text. |

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| **STUDY SITE** | Click or tap here to enter text. | **REPORT SUBMISSION DATE** | Click or tap to enter a date. |

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| *(To be filled out by the Principal Investigator)*   1. **NATURE OF REPORT**   **MINOR PROTOCOL DEVIATION** *(non-systematic protocol non-compliance with minor consequences, in terms of its effect on the participant’s/ subject’s right, safety or welfare, or the integrity of study data; includes deviations that are administered in nature)*  **MAJOR PROTOCOL DEVIATION OR PROTOCOL VIOLATION***( persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put participant’s safety at risk)* | |
| 1. **DESCRIPTION OF REPORTED DEVIATION / VIOLATION:**   Click or tap here to enter text. | |
| 1. **DESCRIPTION OF INVESTIGATOR CORRECTIVE ACTION:**   Click or tap here to enter text. | |
| 1. **SPONSOR ASSESSMENT OF SEVERITY :**   **MAJOR  MINOR** | |
| 1. **DESCRIPTION OF SPONSOR CORRECTIVE ACTION:**   Click or tap here to enter text. | |
| **DATE OF DEVIATION REPORT :** Click or tap to enter a date. | **REPORTED BY:** Click or tap here to enter text.  PRINCIPAL INVESTIGATOR SIGNATURE OVER PRINTED NAME |
| **DATE OF REPORT:** Click or tap to enter a date. |

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| ***(To be assesed by Primary Reviewers)*** | | |
| 1. **DOES THE IMPLEMENTATION OF THE SUBMITTED CORRECTIVE AND PREVENTIVE ACTION (CAPA) PLAN WERE APPRORIATE?** | **YES**  **NO** | **JUSTIFICATION OF RECOMMENDATIONS:**  Click or tap here to enter text. |
| 1. **Is there any effect of the Protocol Deviation (PD) / Protocol Violation (PV) on scientific integrity and participant safety?** | **YES**  **NO** | **JUSTIFICATION OF RECOMMENDATIONS:**  Click or tap here to enter text. |

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| **RECOMMENDED ACTION**  **UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION**  **REQUEST INFORMATION: *(specify)*** Click or tap here to enter text.  **RECOMMENDATION FURTHER ACTION:**  Suspend the study (until additional information is made available and reviewed)  Suspend the study (until recommendations are implemented by the PI and found to be  satisfactory) / Site Visit  Suspension of recruitment  Withdrawal of Ethical Clearance   |  | | --- | | **DESCRIBED PREVENTIVE ACTION TO BE TAKEN**  Click or tap here to enter text. |  |  |  |  | | --- | --- | --- | | **PRIMARY REVIEWER** | **REVIEWED BY:**  Click or tap here to enter text.  **Signature over Printed Name** | **DATE:**  Click or tap to enter a date. | | **FIERC CHAIR** | **APPROVED BY:**  Click or tap here to enter text.  **Signature over Printed Name** | **DATE:**  Click or tap to enter a date. | |