**REPORTABLE NEGATIVE EVENT REPORT**

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| **FIERC PROTOCOL CODE** | Click or tap here to enter text. | **SUBMISSION 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** |  | **CONTACT INFORMATION** | Tel. No: |
| Mobile No: |
| **CO- PRINCIPAL INVESTIGATORS (If Any)** |  | Email: |

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| **INSTITUTION** | |  | | | | |
| **ADDRESS OF INSTITUTION** | |  | | | | |
| **TEL. NO.** |  |  | **MOBILE NO.** |  | **EMAIL:** |  |

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| **APPROVAL DATE:** | Click or tap to enter a date. | **ETHICAL CLEARANCE EFFECTIVITY PERIOD** | Click or tap to enter a date. |

**RNE REPORT**

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| **STUDY SITE** | **Single Site**  **Multi-Site** | **DATE OF REPORTABLE EVENT** | Click or tap to enter a date. |

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| **WHERE DID THE NEGATIVE EVENT OCCUR?** | Click or tap here to enter text. |

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| **START OF THE STUDY** | Click or tap to enter a date. | **EXPECTED END OF THE STUDY** | Click or tap to enter a date. |

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| **NUMBER OF ENROLLED PARTICIPANTS** |  | **NUMBER OF REQUIRED PARTICIPANTS** |  |

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| **DESCRIPTION OF NEGATIVE EVENTS (HARMS, RISKS)** | Involving Participants  Involving members of the Study Team  Involving Data Safety and Integrity |

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| **REPORT STATUS:** | Please indicate whether this is the first time this event has been reported to the FIERC or if it is a follow-up report | | |
| Not Applicable | | Initial Review | Follow-up Report  Date of Initial Report \_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **EVENT SUMMARY** | Please provide a **narrative summary of the event** that occurred. The summary should include the following events:   1. How the event is related to the research (An event is considered related to the research if the cause of the event is deemed related or possibly related to research participation); 2. The date the event occurred; 3. The research team member who handles the event; 4. The date the team became aware of the event; 5. A description of the event and the subjects that were affected; 6. Immediate and follow-up actions taken in response to the event to date; and 7. What is the status of the follow-up of this event: Resolved or Unresolved |
| Click or tap here to enter text. | |

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| **SUPPORTING REPORTS** | Please identify any other entities that have been informed of this event (e.g. Publica Safety, Funding Agency, etc.) if applicable. Please provide copies of any event-related correspondence (including email) with the mentioned entities as attachments. |
| Click or tap here to enter text. | |

***FIERC USE ONLY***

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| **RISK / BENEFIT ASSESSMENT:** | In light of this event, please re-assess the risk / benefit of the study and provide rationale for whether or not the protocol exposes subjects to more risk than initially anticipated and whether risks to subject remain reasonable in relation to the anticipated benefits (if any): |
| Click or tap here to enter text. | | |

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| **RECOMMENDATIONS:** | Recommend suspension of the study until risk is resolved  Withdrawal of ethical clearance  Submission of a plan to mitigate risk / harm  Require an amendment to the protocol  Uphold original ethical clearance |
| **JUSTIFICATION FOR THE RECOMMENDATIONS** | Click or tap here to enter text. |

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| **Principal Investigator Name and Signature** |  |
| **Date:** | Click or tap to enter a date. |