**SAE AND SUSAR FORM**

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

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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. | **SPONSOR / FUNDING AGENCY** | Click or tap here to enter text. |

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| **SERIOUS ADVERSE EVENT** | **DATE SAE HAPPENED** |
|  | **DATE** Click or tap to enter a date. |
| **TREATMENT** |
| [ ] Resolved | [ ] On- Going |

|  |  |
| --- | --- |
| **SERIOUSNESS** | **RELATION TO** |
| [ ] Death[ ] Life-threatening[ ]  **Hospitalization**[ ] Initial [ ] Prolonged[ ] Disability / Incapacity[ ] Congenital Anomaly[ ] Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ] Drug[ ] Food Products | [ ] Study[ ] Not Related[ ] Possibly[ ] Probably[ ] Definitely related[ ] Unknown |

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| **PARTICIPANT’S INTIAL / NUMBER** |  | **AGE (in years)** | [ ] Male[ ] Female |

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| **RESEARCH PARTICIPANT’S HISTORY** | **LABORATORY FINDINGS** |
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| ***To be filled-out by FIERC***

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| **TYPE OF REVIEW** | **DATE OF FIERC MEETING**  |
| [ ] Expedited | [ ] Full Board | Click or tap to enter a date. |

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| **DOCUMENT RECEIVED BY:**Click or tap here to enter text.**Signature over Printed Name**Click or tap to enter a date.**DATE** | **REVIEWED BY:**Click or tap here to enter text.**Signature over Printed Name**Click or tap to enter a date.**DATE** |

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| **REVIEWER’S RECOMMENDATIONS** |
| **Changes to the protocol recommend** | [ ] NO | [ ] YES |
| **Comments:** |
| **Changes to the informed consent form recommend** | [ ] NO | [ ] YES |
| **Comments:** |  |  |

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| --- |
| **FIERC ACTION:** |
| [ ] Request an amendment |
| [ ]  **Protocol** | [ ] Informed Consent Form |
| [ ] Further information or action required |
| [ ] Take note and continue monitoring |
| [ ] Notation with no further action require |
| [ ] Suspension or termination of recruitment / study |

**Click or tap here to enter text.****FIERC SAE Chair****Click or tap to enter a date.****Date** |