**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 |

|  |  |
| --- | --- |
| **RESEARCH PARTICIPANT’S HISTORY** | **LABORATORY FINDINGS** |
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| ***To be filled-out by FIERC***     |  |  |  | | --- | --- | --- | | **TYPE OF REVIEW** | | **DATE OF FIERC MEETING** | | Expedited | Full Board | Click or tap to enter a date. |  |  |  | | --- | --- | | **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** |  |  |  |  | | --- | --- | --- | | **REVIEWER’S RECOMMENDATIONS** | | | | **Changes to the protocol recommend** | NO | YES | | **Comments:** | | | | **Changes to the informed consent form recommend** | NO | YES | | **Comments:** |  |  |  |  |  | | --- | --- | | **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** |