|  |
| --- |
| **EH Horizontal Logo RGB - Primary**  **Safety Report Form**  A safety report is required at Eastern Health for all safety events RELATED to the Investigational Product/Procedure (IP). Studies sponsored by Eastern Health are required to report ALL safety events.  This form should only be used for submissions directly to the Eastern Health Office of Research & Ethics via email: [ethics@easternhealth.org.au](mailto:ethics@easternhealth.org.au) . If a safety report is required to be submitted to the reviewing Human Research Ethics Committee (HREC) such as for a Suspected Unexpected Serious Adverse Reaction (SUSAR) or Significant Safety Issue (SSI) please submit to HREC via Ethical Review Manager (ERM). If the study has been reviewed by an external reviewing HREC under the National Mutual Acceptance scheme please provide the report with HREC acknowledgement to our office.  For further information & definitions please see the [NHMRC Safety Monitoring Guidelines](https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods) (please note Eastern Health has additional local requirements to those outlined in the guidelines) |

**Study Details**

|  |  |  |  |
| --- | --- | --- | --- |
| **Study title** | Click here to enter text. | | |
| **Local Reference Number/ERM ID** | Click here to enter text. | **Date of Report** | Click here to enter a date. |
| **Principal Investigator** | Name: Click here to enter text.  Email: Click here to enter text.  Contact Number: Click here to enter text. | | |
| **Contact Person** | Name: Click here to enter text.  Email: Click here to enter text.  Contact Number: Click here to enter text. | | |
| **Sponsor** | Click here to enter text. | | |

**Safety Event**

|  |  |  |  |
| --- | --- | --- | --- |
| **Date of Event** | Click here to enter a date. | | |
| **Type of Event** | Choose an item. | | |
| **SAE Type per IB** | Choose an item. |  |  |
| **Relationship to IP** | Choose an item. |  |  |
| **Participant Trial ID #** |  | | |
| **Eastern Health Site** | Choose an item or enter text. | | |
| **Description of Event** | Click here to enter text. | | |
| **Actions taken** | Click here to enter text. | | |
| **Status of Event** \*Please provide a follow-up report if the event is ongoing | Choose an item. | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigator Signature** |  | **Date** | Click here to enter a date. |

**\*Accepted Signatures are:**

1. **A copy of this form, signed in wet ink, scanned and forwarded to our office electronically.**
2. **Unsigned, completed form, forwarded to our office electronically via PI/AI email address.**
3. **Unsigned, completed form forwarded to our office electronically but has cc’d the PI or AI**
4. **Signature MUST NOT be a Copy and Paste only – Forms will be returned.**

***These options are to indicate and verify the PI/AI’s knowledge and completion of this report.***

**Definitions:**

**Adverse Event (AE) -** Any untoward medical occurrence in a patient or clinical trial participant administered a medicinal product and that does not necessarily have a causal relationship with this treatment.

**Adverse Reaction (AR) -** Any untoward and unintended response to an investigational medicinal product related to any dose administered.

**Serious Adverse Event (SAE)/Serious Adverse Reaction (SAR)** - Any adverse event/adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.

**Significant Safety Issue (SSI) -** A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.

**Suspected Unexpected Serious Adverse Reaction (SUSAR) -** An adverse reaction that is both serious and unexpected.