This Safety Event Report is to be used to capture a ‘Reportable Event’ in research projects. It is also compulsory for any Reportable Event to be submitted in the [Safety Reporting Learning System](https://srls.health.local/) (SRLS): This Safety Event form once completed can be uploaded into the SRLS. For multi-site projects, the PI should provide a copy of this Safety Report to the Sponsor or may use the Sponsor provided form.

**Reportable Events include:**

|  |  |
| --- | --- |
| Adverse Event (AE) | Any untoward medical occurrence in a patient or clinical trial participant administered a medicinal product and 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. (Comment: All adverse events judged by either the reporting investigator or the sponsor as having a reasonable possibility of a causal relationship to an investigational medicinal product would qualify as adverse reactions. The expression ‘reasonable causal relationship’ means to convey, in general, that there is evidence or argument to suggest a causal relationship). |
| Non-Serious Breach / Deviation | A deviation is any breach, divergence or department from the requirements of Good Clinical Practice (GCP) or the protocol that does not have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the research project. If a deviation is a serious breach, is should be reported as a Suspected or Serious Breach. |
| Suspected Breach | A report that is judged by the reporter as a possible serious breach but has yet to be formally confirmed as a serious breach by the Sponsor. |
| Serious Breach | A breach of the protocol or Good Clinical Practice (GCP) that is likely to affect to a significant degree:   * the safety or rights of a participant; or * the reliability and robustness of the data generated in the project. |
| 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 of the trial. Often SSIs do not fall within the definition of a Suspected Unexpected Serious Adverse Reaction (SUSAR), thus are not reported as SUSARs but require other action such as the reporting of an urgent safety measure (USM), an amendment, a temporary halt or early termination of a trial. |
| Suspected Unexpected Serious Adverse Reaction (SUSAR) | An adverse reaction that is both serious and unexpected. |
| Unanticipated Serious Adverse Device Effect (USADE) | A serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report. |
| Urgent Safety Measure (USM) | A measure required to be taken in order to eliminate an immediate hazard to a participant’s health or safety. |

**Reporting Exclusions:**

|  |  |
| --- | --- |
| Reference Safety Information | The information contained in either an Investigator’s Brochure (IB) or an approved Australian Product Information (or another country’s equivalent) that contains the information used to determine what adverse reactions are to be considered expected adverse reactions and, on the frequency, and nature of those adverse reactions. |
| Safety Critical Adverse Events | Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations that should be reported to the sponsor according to the reporting requirements specified in the protocol. |

| **1** | **RESEARCH PROJECT** | |
| --- | --- | --- |
| 1.1 | Project Reference Number: |  |
| 1.2 | Project Title: |  |
| 1.3 | Site Principal Investigator: |  |
| 1.4 | Health Service Site *(select one)*: | Royal Hobart Hospital  Launceston General Hospital  North West Regional Hospital  Mersey Community Hospital  Ambulance Tasmania  Department of Health  Other |
| 1.5 | *(If Other selected at 1.4)*  Specify Details of Health Service Site: |  |
| 1.6 | Department / Location of Safety Event: |  |
| 1.7 | Lead HREC Name: |  |
| 1.8 | Other HREC Reference: |  |
| 1.9 | Sponsor: |  |

| **2** | **DETAILS OF SAFETY EVENT** | |
| --- | --- | --- |
| 2.1 | Safety Event Date *(dd/mm/yyyy)*: |  |
| 2.2 | Type of Safety Event *(select all that apply)*: | Adverse Event / Adverse Reaction  Non-Serious Breach / Deviation  Suspected Breach  Serious Breach  Serious Adverse Event (SAE)  Serious Adverse Reaction (SAR)  Significant Safety Issue (SSI)  Suspected Unexpected Serious Adverse Reaction  (SUSAR)  Unanticipated Serious Adverse Device Effect  (USADE)  Urgent Safety Measure (USM) |
| 2.3 | Has this Safety Event been reported in the Safety Reporting and Learning System (SRLS)? | Yes *(Complete Section 2.4)*  No – Complete Safety Event From in the [SRLS](https://srls.health.local/)  N/A *(Complete Section 2.5)* |
| 2.4 | *(if Yes selected at 2.3)*  SRLS ID Number(s): |  |
| 2.5 | *(if N/A selected at 2.4)*  Details: |  |
| 2.6 | Has this Safety Event been reported to the Lead HREC/Sponsor? | Yes *(Complete Section 2.7)*  No *(Complete Section 2.8)*  n/a |
| 2.7 | *(if Yes selected at 2.6)*  Details: |  |
| 2.8 | *(if No or n/a selected at 2.6)*  Details: |  |
| 2.9 | What immediate actions were taken in response to the Safety Event? | Urgent Safety Measure (USM)  Notification of Amendment  Temporary Halt of a Trial for Safety Reasons  Early Termination of Trial for Safety Reasons |
| 2.10 | What further corrective actions were or will be taken in response to the Safety Event? | (*this may include completing a Root Cause Analysis or case review)* |
| 2.11 | Has the Therapeutic Goods Associated (TGA) been notified? | Yes *(Complete Section XX)*  No *(Complete Section XX)*  n/a |
| 2.12 | TGA actions: Should this differentiate notification is only required for unapproved therapeutic goods? |  |
| 2.13 | Has the safety event been reported to the Data Safety Monitoring Board (DSMB), Sponsor or other Safety Monitoring group for the project? | Yes *(Complete Section xx)*  No *(Complete Section xx)*  n/a |
| 2.14 | Open Disclosure. Was this safety event disclosed/discussed with the participant or their guardian? | Yes  No  n/a |
| 2.15 | Will this participant be withdrawn from the Study? | Yes  No  n/a |
| 2.16 | Are there any additional safety concerns for other participants? | Yes  No  n/a |
| 2.17 | Will there be changes to the Protocol in response to the Safety Event? | Yes  No  n/a |
| 2.18 | Will there be changes to the Participant Information and Consent Form (PICF) in response to the Safety Event? | Yes  No  n/a |
| 2.19 | Will there be changes to the Investigator’s Brochure (IB)? | Yes  No  n/a |
| 2.20 | Supporting documentation attached: | Yes  No  n/a |

| **3** | **DETAILS OF SAFETY EVENT REVIEW** | |
| --- | --- | --- |
| 3.1 | Summary of analysis/investigation: |  |
| 3.2 | Contributing Factors: |  |
| 3.3 | Response / Further Actions: |  |
| 3.4 | Date event closed in SLRS: |  |

| **4** | **DECLARATION** *(add more tables as required)* | |
| --- | --- | --- |
| **4.1** | **CPI / PI DECLARATION** | |
| * The information provided is complete and correct. * The project is being conducted in compliance with the *NHMRC National Statement on the Ethical Conduct in Human Research* (2018) and the *Australian Code for the Responsible Conduct of Research* (2018) and *Note for Guidance on Good Clinical Practice* (CPMP/ICH/135/95). * I will provide any necessary documentation during the investigation. * I will adhere to the conditions of approval stipulated by the HREC and RGO and will cooperate with RGO and HREC monitoring requirements. * I will inform the HREC, the RGO and the delegated department or Divisional Head if the research project ceases before the expected date. * I will discontinue the research if the HREC withdraws ethical approval or the authorising authority at the site withdraws authorisation. * I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, the RGO, the sponsor or an independent body for audit and monitoring purposes. | | |
| 4.1 | Name: |  |
| 4.2 | Position: |  |
| 4.3 | Signature: |  |
| 4.4 | Date *(dd/mm/yyyy)*: |  |

| **4.5** | **HEAD OF DEPARTMENT / DIVISIONAL DIRECTOR DECLARATION** *(or equivalent)* | |
| --- | --- | --- |
| * I have read the research project safety report. * I agree that this safety event have been appropriately investigated and systems to improve the conduct and governance of research if required from the investigation will be implemented. * I have discussed this safety report, and any implications for this department, with the Principal Investigator. | | |
| 4.6 | Comments: |  |
| 4.7 | Name: |  |
| 4.8 | Signature: |  |
| 4.9 | Date *(dd/mm/yyyy)*: |  |

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| **5** | **ACTIONS** | |
| --- | --- | --- |
| 5.1 | Safety Report Validation Date *(dd/mm/yyyy)*: |  |
| 5.2 | RGO Actions: |  |
| 5.3 | Name: |  |
| 5.4 | Position: |  |
| 5.5 | Signature: |  |
| 5.6 | Date *(dd/mm/yyyy)*: |  |