Safety Monitoring Report

**This Safety Monitoring Report is the approved mechanism for informing the Southern Adelaide Clinical Research Ethics Committee (SAC HREC) and/or SALHN of any safety issues that the sponsor of a clinical drug or clinical device trial has identified. The form should be submitted to the Office for Research at** Health.SALHNOfficeforresearch@sa.gov.au**.**

## Overview

Safety monitoring processes should be developed by the Sponsor based on the risk, size and complexity of the proposed research. If the Institution is named as the trial sponsor, the institution will also assume the sponsor responsibilities set out in this document. It is the sponsors responsibility to determine the most appropriate arrangements for ongoing monitoring and be prepared to justify these arrangements to the reviewing HREC.

### Serious Adverse Event related to the study and unexpected

The HREC will need to be notified of significant safety issues reported as Urgent Safety Measures (USM’s – within 72 hours), Significant Safety Issue Amendments (SSI – within 15 days) and any reason a temporary halt/early termination of a trial has been recommended. Investigator brochure updates related to safety (or interim addendums) should also be reported to the HREC as an SSI.

### HREC responsibilities

The approving HREC will:

* satisfy itself that the sponsor’s ongoing safety monitoring arrangements are adequate, including the justification for appointing/not appointing a Data Safety Monitoring Board and any ‘stopping rules’ or criteria for withdrawing individual participants from the trial.
* keep under review the adequacy and completeness of the informed consent process and documentation in the light of new information about risks and benefits
* assess whether changes to the risk-benefit ratio that are reported by the sponsor are compatible with continued ethical approval
* advise the TGA, investigators and their institutions of any decision to withdraw approval

### Institutional responsibilities

On behalf of the Institution, the Research Governance Officer will:

* assess whether any safety reports received impact on medico-legal risk, the responsible conduct of research, adherence to contractual obligations or the trial’s continued site authorisation and, where applicable, facilitate the implementation of corrective and preventative action.

### Annual Safety Report

Serious Adverse Events not related to the study and suspected unexpected serious adverse reactions (line listings) do not need to be reported to the SAC HREC. However, sponsors must provide the HREC with an **Annual Safety Monitoring Report** that supports trial oversight including a clear summary of the evolving safety profile of the trial and also evidence that the sponsor is conducting its ongoing safety monitoring appropriately. In this report, they will demonstrate that they have categorised the safety reports received from investigators and have reported all suspected unexpected serious adverse reactions occurring in Australian participants to the Therapeutic Goods Administration (TGA).

* for fatal or life threatening Australian SUSARs, immediately, but no later than 7 calendar days
* after being made aware of the case, with any follow-up information within a further 8 calendar days
* for all other Australian SUSARs, no later than 15 calendar days after being made aware of the case

For further information please visit [NHMRC Safety Monitoring and Reporting in Clinical Trials involving therapeutic goods](file:///C%3A%5CUsers%5Cgas013%5CDownloads%5CNHMRC-guidance-safety-monitoring-and-reporting%20%284%29.pdf)

|  |
| --- |
| **Date**: Click here to enter text. |
| **Office for Research reference number:** Click here to enter text. |
| **Principal Investigator:**Click here to enter text. |
| **Project title:**Click here to enter text. |
| **Documents being submitted:**Click here to enter text. |
| **The documents support the following Safety Events – see Definitions - Appendix 1:**[ ]  **Annual Safety Monitoring Report**[ ]  **Urgent Safety Measure – no later than 72 hours of measure being taken**[ ]  **Significant Safety Issue Amendment – no later than 15 calendar days of sponsor awareness**[ ]  **Temporary halt of a trial for safety reasons – without undue delay and no later than 15 calendar days of the sponsor’s decision to halt the trial**[ ]  **Early termination of a trial for safety reasons – without undue delay and lo later than 15 calendar days of the sponsors decision to terminate the trial**Click here to enter text. |

|  |  |
| --- | --- |
| Reasons for safety issue | Click here to enter text. |
| Corrective Action Taken | Click here to enter text. |
| Further action planned/preventative action | Click here to enter text. |
| The implications of these events for the conduct of the trial/research are: | Please select one of the following:[ ]  The trial will continue without alteration[ ]  The trial will continue with the PICF having been updated to reflect the amended information[ ]  The trial will continue; however, these documents raise concerns that the Principal Investigator will monitor and report on as appropriate[ ]  The trial has been temporarily halted Reason:Click here to enter text.  Scope of the halt Click here to enter text.[ ]  Early termination of a trial for safety reasons Reason: Click here to enter text.[ ]  Other action is required: Click here to enter text. |

Declaration

|  |
| --- |
| I confirm the information provided in this form is correct.**Chief / Principal Investigator:** Click here to enter text.**Date**: Click here to enter text.Signature:  |

For more information

**SALHN Office for Research, Ward C / Room 6A – 219 Flinders Medical Centre, Telephone: (08) 8204 6453; Email:** **Health.SALHNofficeforresearch@sa.gov.au**[www.sahealth.sa.gov.au/SALHNresearch](http://www.sahealth.sa.gov.au/SALHNresearch)

## Appendix 1 – Definitions

### Adverse Avent

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.

### 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. Life-threatening in the definition of a serious adverse event or serious adverse reaction refers to an event in which the participant was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe. Medical and scientific judgement should be exercised in deciding whether an adverse event/

reaction should be classified as serious in other situations. Important medical events that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the participant or may require intervention to prevent one of the other outcomes listed in the definition above should also be considered serious.

### Suspected Unexpected Serious Adverse Reaction (SUSAR)

An adverse reaction that is both serious and unexpected

### Unexpected Adverse Reaction

An adverse reaction, the nature or severity of which is not consistent with the Reference Safety Information. The RSI should be contained in the Investigator’s

### Urgent Safety Measure (USM)

A measure required to be taken in order to eliminate an immediate hazard to a participant’s health or safety. Note: This type of significant safety issue can be instigated by either the investigator or sponsor and can be implemented before seeking approval from HRECs or institutions.

### Significant Safety Issue amendment (SSI)

A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or contact of the trial

### 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.

## Appendix 2 - Safety Monitoring and Reporting in Clinical Trials Involving therapeutic goods, NHMRC, 2016

