Protocol/GCP Suspected or Serious Breach Report

**Researchers are required to complete this form when there is a suspected/serious protocol breach. They will need to submit it to the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) at** Health.SALHNOfficeforresearch@sa.gov.au **or Lead HREC.**

### Overview

Deviations from GCP or the protocol should lead to ‘prompt action by the sponsor to secure compliance’. GCP requires all deviations to be reported to, and collated by the sponsor so

that corrective and preventative action can be implemented and so that their impact on the analysis

of the data can be considered when the clinical study report is produced. Minor protocol deviations do not need to be reported to the HREC, however confirmed serious breaches do.

The role of an HREC in reviewing serious breaches is to evaluate the impact on continued ethical acceptability of the study and to satisfy itself that the breach is managed appropriately. For example, through an amendment to trial documentation. HRECs may also assess whether any corrective and/or preventative actions implemented or planned are appropriate and have adequately addressed the underlying issue. The HREC will notify the TGA if trials conducted under the CTX/CTN scheme should a serious breach lead to the suspension or withdrawal of the ethics approval for the trial.

### Definitions

#### Serious Breach:

A deviation from Good Clinical Practice or the protocol that is likely to affect to a significant degree:

* The safety or rights of a trial participant, or
* The reliability and robustness of the data generated in the clinical trial.

The sponsor must report serious breaches to the Site PI and reviewing HREC within 7 calendar days of confirming a serious breach has occurred and provide follow-up reports when required.

#### Suspected Breach

A deviation 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. Sponsors have primary responsibility for determining whether any suspected breach meets the definition of a serious breach. If the sponsor is unsure whether a potential serious breach has significant impact on the rights or safety of participants, they should contact the reviewing HREC for advice

#### Minor Protocol Deviation:

Any breach, divergence, or departure from the requirements of Good Clinical Practice or the clinical trial protocol – do not need to be reported to HREC

### Reporting requirements

HRECs need only be made aware of suspected/serious breaches that have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the clinical trial. Minor protocol deviations do not need to be reported to the HREC.

Written details need to be provided to the SAC HREC when there are:

* Safety or ethical implications for the participant(s);
* The scientific integrity of the study is affected (normally the sponsor will advise this)
* The protocol methodology has caused a serious breach or
* The conduct of the study caused a serious breach. If there is no site impact, the incident would be classified as a protocol deviation and does not need to be reported

The Institution should also be notified of serious breaches occurring at their site by the Principal Investigator as it may impact on medico-legal risk, the responsible conduct of research, or adherence to contractual obligations.

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| --- |
| **Date**: Click here to enter text. |
| **Office for Research reference number:** Click here to enter text. |
| **Site event occurred at:** Click here to enter text. |
| **Project title**: Click here to enter text. |
| **This form is reporting** **a**:Suspected Breach [ ]  Serious Breach [ ]  |
| **Describe the event here:** Click here to enter text. |
| **Is there an impact to the participant’s safety?** [ ] Yes [ ] No |
| **Describe what impact the breach has had on participant safety and/or the research project:** Click here to enter text. |
| **What corrective actions have been taken?** Click here to enter text. |
| **What preventative actions will be taken to avoid a reoccurrence? Click here to enter text.** |
| **Has the sponsor provided any letters or reports for this event?**[ ] Yes (If yes please submit with this form)[ ] No |
| **Does the PICF require updating?** [ ] Yes  **(please include document)** [ ] No |
| **Does the protocol require updating** [ ] Yes **(please include document)** [ ] No |

### Declaration

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| 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:  |

Email completed form to: Health.SALHNOfficeforResearch@sa.gov.au

* Only Suspected/Serious breaches needs to be reported to the SAC HREC -minor protocol deviations do not
* For multi-site studies, please send this form to the Coordinating Principal Investigator for review. It is the CPI’s responsibility to submit this form to the lead HREC (Local RGO only needs to be advised if further action is required)
* Please submit any updated PICFs or protocol as an amendment - ensure any attachments being submitted can be read easily.
* Please consider this report acknowledged by the Office for Research on receipt of the automated email response. The Office for Research will only be in contact if further information is required.

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)