

SITE NON-COMPLIANCE LOG

Trial Title:			
Participating Site Name:		Site Investigator Name:	

GUIDANCE:

This log is to be used to record all serious breaches that have occurred at either the site level or sponsor level for your clinical research study. It is required for both interventional and non-interventional clinical research studies.

This log is complementary to, and does not replace, the form reporting individual serious breaches to Ethics Committees, Research Governance Office and/or Regulatory Authorities (e.g. TGA).

INSTRUCTIONS:

Record all serious breaches as they occur using this log, to ensure completeness and accuracy of the data.

A corresponding Non-Compliance Report Form must be submitted to the Sponsor for reported serious breaches.

Number each page and maintain this log in your study's Investigator Site File (ISF). At the conclusion of the study, identify the final page of the log by checking the box in the footer.

Remove this Guidance Sheet before use of the log.

SERIOUS BREACH DEFINITION:

A serious breach is a breach of Good Clinical Practice (GCP) or the protocol that is likely to affect to a significant degree:

- a. The safety or rights of a trial participant; and/or
- b. The reliability and robustness of the data generated in the clinical trial.

SITE NON-COMPLIANCE LOG

Trial Title:		Protocol No:	
Participating Site Name:		Site Investigator Name:	

SERIOUS BREACH DEFINITION:

A serious breach is a breach of Good Clinical Practice (GCP) or the protocol that is likely to affect to a significant degree:

- b. The safety or rights of a trial participant; and/or
- c. The reliability and robustness of the data generated in the clinical trial.

	Participant ID No (PID#)	Date Serious Breach Occurred <i>(dd/MMM/yyyy)</i>	Description of Serious Breach	Non-Compliance Category <i>1. Inclusion or Exclusion 2. Informed consent 3. Randomisation 4. Intervention Assessment 5. Safety reporting 6. Excluded intervention/medication 7. Discontinuation 8. GCP 9. Sponsor 10. Other - specify</i>	Sponsor's Recommended Corrective & Preventative Action (CAPA) Description and Status <i>(i.e. Completed or Ongoing)</i>	Date of Resolution at Site <i>i.e. Date CAPA Completed (dd/MMM/yyyy)</i>	Date Serious Breach Reported to EC/RGO <i>(dd/MMM/yyyy)</i>	Date Serious Breach Reported to Regulatory Authority <i>(if applicable) (dd/MMM/yyyy)</i>
1.								
2.								
3.								
4.								
5.								

	Participant ID No (PID#)	Date Serious Breach Occurred <i>(dd/MMM/yyyy)</i>	Description of Serious Breach	Non-Compliance Category <i>1. Inclusion or Exclusion 2. Informed consent 3. Randomisation 4. Intervention Assessment 5. Safety reporting 6. Excluded intervention/medication 7. Discontinuation 8. GCP 9. Sponsor 10. Other - specify</i>	Sponsor's Recommended Corrective & Preventative Action (CAPA) Description and Status <i>(i.e. Completed or Ongoing)</i>	Date of Resolution at Site <i>i.e. Date CAPA Completed (dd/MMM/yyyy)</i>	Date Serious Breach Reported to EC/RGO <i>(dd/MMM/yyyy)</i>	Date Serious Breach Reported to Regulatory Authority <i>(if applicable) (dd/MMM/yyyy)</i>
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								