

NON-COMPLIANCE REPORT FORM

Protocol Acronym or #	
Protocol Title:	
Sponsor-Investigator/CPI:	

*This form is to be used for reporting a suspected *serious breach to the Sponsor-Investigator/Coordinating Principal Investigator (CPI) of an MCRI-sponsored trial. Externally sponsored trials (either Collaborative Research Group, investigator-initiated or commercial) should have their own process for reporting suspected serious breaches.*

This form should be modified to include trial-specific details of the Trial Coordinator and details of where participating sites should email completed Non-Compliance Report Forms.

*It is **highly recommended** that the remaining details of the form are not modified.*

Ensure that this green guidance text is deleted, prior to finalising your trial-specific version of your form.

Participating sites must report all suspected serious breaches to the Sponsor within **72 hours** of the site staff becoming aware of the event using this form.

Completed Non-Compliance Report Forms must be emailed to the Trial Coordinator at: XXXX@XXX.XX

A copy of the email and completed Non-Compliance Report Form must be retained in the Investigator Site File (SIF).

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:

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

For further information about managing and reporting non-compliance, including serious breaches, refer to [MCTC123 V1.0 SOP Management of Non-Compliance – Protocol Deviations and Serious Breaches](#).

The SOP contains further information about the responsibilities of the Site Principal Investigator and the Sponsor-Investigator/CPI with regards to managing non-compliance, including serious breaches.

1. SUSPECTED BREACH DESCRIPTION

Date of Report: (dd/MMM/yyyy)	
Date of Suspected Breach: (dd/MMM/yyyy)	
Site Name:	
Participant ID No (PID#):	

2. SITE ASSESSMENT OF THE PROTOCOL DEVIATION / SERIOUS BREACH		
Is remedial or further action required?	<input type="checkbox"/> Yes (see below)	<input type="checkbox"/> No
<p>CAPA (Corrective and Preventive Action): Outline the action(s) taken to both correct and prevent recurrence of this (suspected) serious breach in the future. More detailed about the actions taken and further actions required must be provided in a formal CAPA plan using the site's local procedure. RCH/MCRI site staff must use the process described in MCTC061 SOP Continuous improvement: a corrective and preventive action (CAPA) plan.</p>		

3. PARTICIPATING SITE DETAILS	
Suspected Serious Breach Reported by:	
Site Investigator Name:	
Site Investigator Signature:	
Date: (dd/MMM/yyyy)	