THIRD PARTY SUSPECTED BREACH REPORT FORM

This form is to be used by MCRI/RCH personnel who are participating in externally-sponsored trials and wish to report a suspected serious breach* to the reviewing Human Research Ethics Committee (HREC).

Completed Third-Party Suspected Breach Report Forms must be emailed **directly** to the reviewing HREC. This report should not be sent via the Sponsor.

A copy of the email and completed Third Party Suspected Breach Report Form must be retained in the Investigator Site File (ISF).

DO NOT USE THIS FORM if the incident has already been reported to the Sponsor, and they have confirmed the occurrence as a Serious Breach. In this circumstance, the Sponsor is responsible for submitting a Serious Breach form to the reviewing HREC.

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.

A Suspected Breach is a report that is judged by the reporter as a possible Serious Breach but has yet to be confirmed as a serious breach by the Sponsor.

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. REPORT DETAILS			
HREC Reference Number:		**Date of this Report:** *(dd/MMM/yyyy)*	
Project Title:			
Protocol Acronym or #			
Name of Sponsor/Sponsor-Investigator/Coordinating Principal Investigator:			
Date of last Sponsor/Sponsor-Investigator/CPI communication about this Suspect Breach: *(dd/MMM/yyyy)*			
Full name of Reporter:			

Phone Number of Reporter:	
Email of Reporter:	
Reporter's role in connection to the research project: *(Tick applicable role)*	☐ Study Coordinator ☐ Research Nurse ☐ Clinical Trial Assistant ☐ Other Specify:_____
2. SUSPECTED BREACH DESCRIPTION	
Date of Suspected Breach: *(dd/MMM/yyyy)*	
Site Name:	
Site Address:	
Participant ID No: *(If applicable)*	
Deviation/Breach Category: *(Tick which applies)*	☐ Inclusion/Exclusion ☐ informed Consent ☐ Randomisation ☐ Intervention ☐ Assessment ☐ Safety Reporting ☐ Excluded Intervention/Medication ☐ Discontinuation ☐ GCP ☐ Other, Specify:_____

Full description of the suspected serious breach, including reason for deliberate deviation from the protocol (if applicable): *Continue on a separate page if necessary.*
Full Description of the potential impact of the suspected breach on: - **Participant safety** - **Participant rights** - **Reliability and robustness of data**
Full description of where, how, and when the suspected serious breach was identified:

3. CORRECTIVE AND PREVENTATIVE ACTION (CAPA)	
CAPA implemented by the Site: *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.*	
4. SITE DETAILS	
Site Investigator Name:	
Signature:	
Date: *(dd/MMM/yyyy)*	