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| **NON-COMPLIANCE REVIEW FORM** |

**Instructions for Form Completion**

1. RCH/MCRI Trial Coordinator to complete Sections 1 and 2.
2. MCRI Sponsor-Investigator/CPI to complete Sections 3-5 and return to the Trial Coordinator via email at [XXXX@xxxx.xxx.xx](mailto:XXXX@xxxx.xxx.xx) within 24 hours of receipt
3. Site PI to complete Section 6 and return to the Trial Coordinator via email at [XXXX@xxxx.xxx.xx](mailto:XXXX@xxxx.xxx.xx) within 24-48 hours of receipt

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| 1. **TRIAL DETAILS** | |
| * 1. **Protocol Acronym or #:** |  |
| * 1. **Protocol Title:** |  |
| * 1. **Sponsor-Investigator/CPI** |  |

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| 1. **SUSPECTED SERIOUS BREACH DETAILS** | | | | |
| * 1. **Date of Report:**   *(dd/MMM/yyyy)* |  | * 1. **Date of Suspected Breach:** *(dd/MMM/yyyy)* | |  |
| * 1. **Site PI Name:** |  | | | |
| * 1. **Site Name:** |  | | | |
| * 1. **Participant ID No (PID#):** |  | | | |
| * 1. **Breach Category:** | ☐ Inclusion/Exclusion | | ☐ Safety Reporting | |
| ☐ Informed Consent | | ☐ Excluded Intervention/Medication | |
| ☐ Randomisation | | ☐ Discontinuation | |
| ☐ Intervention | | ☐ GCP | |
| ☐ Assessment | | ☐ Other; Specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

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| 1. **ASSESSMENT OF THE SUSPECTED SERIOUS BREACH** | |
| * 1. **Does this suspected serious breach impact on participant safety or the reliability/robustness of trial data?** | ☐ Yes – Complete questions 3.2 to 3.4 and skip question 3.5.  ☐ No – Skip questions 3.2 to 3.4. Go to question 3.5. |
| * 1. **Does the serious breach impact participant safety or the reliability/robustness of trial data?** | ☐ Impacts participant safety  ☐ Impacts reliability/robustness of trial data |
| * 1. **Is the serious breach isolated or systemic?** | ☐ Isolated  ☐ Systemic |
| * 1. **CAPA (Corrective and Preventive Action):**   *Outline below the action(s) taken to both correct and prevent recurrence of this Protocol Deviation / Serious Breach event in the future and/or any further recommendations to be communicated to Site, addressing responses provided to Questions 3.1 -3.4. Sites should be instructed to provide more detailed information about the actions taken and further actions required 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.* | |
| * 1. **Sponsor justification for why the suspected serious breach is not a serious breach:**   *Complete this section if the answer to Question 3.1 was “NO”.*  *Justify below why and how you came to the conclusion that the suspected serious breach is not serious breach* | |

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| 1. **OUTCOME OF REVIEW**  *Consider details outlined in your response provided to Q 3.4 above, when responding to Q’s 4.1-4.4 below.* | |
| * 1. **Is corrective action required by the site?** | ☐ Yes  ☐ No |
| * 1. **Are measures to prevent recurrence required?** | ☐ Yes  ☐ No |
| * 1. **Is additional site training required?** | ☐ Yes  ☐ No |
| * 1. **Does study documentation require updating?** | ☐ Yes  ☐ No |

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| 1. **NON-COMPLIANCE REPORT FORM REVIEW UNDERTAKEN BY:** | |
| * 1. **Sponsor-Investigator/Delegate Name:** |  |
| * 1. **Sponsor-Investigator/Delegate Signature:** |  |
| * 1. **Date:** *(dd/MMM/yyyy)* |  |

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| 1. **PARTICIPATING SITE ACKNOWLEDGEMENT** |
| I acknowledge and understand the above Sponsor response. I agree to report this serious breach to the Competent Authority/Ethics Committee/Research Governance Office (in line with local regulatory requirements). |
| **SITE PRINCIPAL INVESTIGATOR:**  **Name:** **Signature:** **Date:** (dd/MMM/yyyy) |

**Note: A signed copy of the Non-Compliance Review Form, acknowledged by the Site PI, must be filed within the Investigator Site File (ISF) at the participating site.**