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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 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 within 24-48 hours of receipt

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| 1. **TRIAL DETAILS**
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| * 1. **Protocol Acronym or #:**
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| * 1. **Protocol Title:**
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| * 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**
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| * 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**
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| 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.**