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| **Protocol title:** | **Protocol Number:** |
| **Sponsor name:** | **SREC #:** |
| **Principal Investigator (PI) name:** | **Site Name:** |

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| 1. **Details of noncompliance:** | | | | | | | | |
|  | | | | | | | | |
| Relevant section(s) of protocol/SOPs  Detail:  Protocol/SOPs title:  Protocol/SOPs number:  Protocol/SOPs version and date: | | | | | | | | |
| **This non-compliance is related to:**  *Please tick (/) relevant box* | | | | | | | | |
| Missed safety / routine test | | | | | | | |  |
| Missed research assessment / procedure | | | | | | | |  |
| Missed study visit | | | | | | | |  |
| Study visit outside of protocol window | | | | | | | |  |
| Informed Consent | | | | | | | |  |
| IMP (\*incorrect doses / IMP stock / expired IMP / others)  \**Delete where applicable* | | | | | | | |  |
| Other aspect of trial | | | | | | | |  |
| **Findings Severity** *Please tick (/) relevant box* | | | | | | | |  |
| Critical |  | Major |  | Minor |  | Others |  |  |

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| 1. **Correction Action and Prevention action (CAPA) :To be completed within 30 working days** |
| Date for completion Correction Action:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  a. Correction Action:  b. Root Cause Analysis (RCA) (To be completed by Auditee)  Description :  Root cause is:  c. Prevention Action: |

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| **Report completed by** | |
| Name |  |
| Signature |  |
| Date |  |
| Role |  |
| **Reviewed by Principal Investigator**  (Not applicable if noncompliance reported by PI)  For multicentre study, a copy of this completed form shall be sent to Chief Investigator (CI) | |
| Name |  |
| Signature |  |
| Date |  |
| Role |  |

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| **Chief Investigator (CI) or Principal Investigator (PI) Assessment** |
| **Categorisation of non-compliance**  *Please tick (/) relevant box:*  Non-compliance \*\*Potential serious breach  \*Refer to SREC if potential serious breach is reported. |
| **CI/PI Justification of categorisation:** |
| **CI/PI name………………………..………. Signature………………………Date…………………………** |

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| **For coordinating centre use only (if applicable):**  Date Coordinating Centre became aware of noncompliance |  |
| Coordinating Centre noncompliance No. |  |
| Current number of similar noncompliance at this site (Repeated noncompliance) |  |

**\*Please send a copy of CI/PI reviewed form to SunMed CRC (For SunMed Funded Research Only)**

Date form received by CRC:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Quality Assessment: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **Initial Categorisation of non-compliance** *Please tick (/) relevant box:*  Non-compliance Potential serious breach | |
| Reviewer  Name………………………………………….. Signature……………………………….. Date…………………………….. | |
| **FOR POTENTIAL SERIOUS BREACH:** | |
| **This event is likely to:** *Please tick (/) relevant box* |  |
| Affect to a significant degree the safety, or physical or mental integrity of the trial subjects |  |
| Affect to a significant degree the scientific value of the trial |  |
| **Date of escalation to Sponsor/Funder** |  |
| **ADDITIONAL COMMENTS (if any):** | |

**Note: The quality team will contact CI/PI if the noncompliance is a potential breach.**