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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: |

|  |
| --- |
| **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…………………………** |

|  |  |
| --- | --- |
| **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 |
| ReviewerName………………………………………….. 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.**