**Non-Compliance Report Form**

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| **Site** |  | **Local Non-compliance No.** |  |
| **Trial Name** |  | **Chief Investigator** |  |
| **EudraCT No.** |  | **IRAS No.** |  |

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| --- | --- | --- |
| (If applicable) Participant Trial ID No. & initials (or other point of ID) | *Initials (or other ID)* | *Trial ID No.* |
| **This non-compliance is related to:** *(Specify general category or type of N/C)* | | |
| **Category of non-compliance:** *May be tailored according to trial (Excel log listing categories to match)* | | |
| Missed safety test |  | |
| Missed routine test |  | |
| Missed research assessment / procedure |  | |
| Missed study visit |  | |
| Study visit outside of protocol window |  | |
| IMP (\*incorrect doses / IMP stock / expired IMP / others)  \**Delete where applicable* |  | |
| Consent |  | |
| Other aspect of trial |  | |
| **Full details of non-compliance:** | | |
| **Relevant section(s) of Protocol/SOPs** *(provide protocol/SOP number and version):* | | |
| **Corrective action(s) taken:** *(document any corrective action(s) taken at the time of non-compliance relating to this instance of the non-compliance. If none could be taken, enter the reason why)*  **Preventative action(s) taken:** *(document any action(s) taken to prevent future similar occurrences of the non-compliance )*  **(If applicable) File Note reference: ……………………….** | | |
| **Report completed by: ………………………Signature: ……………………Date: ………………………**  **Reviewed by PI: …..…………………………Signature: ……………………Date: ………………………**  *(If different from above)*  **Sites to send a copy of PI reviewed form to the Trial Coordinator** | | |

**CHIEF INVESTIGATOR (CI) ASSESSMENT**

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| **Categorisation of non-compliance** (*tick relevant box):*  Type 2 Type 3  Reportable minor Reportable major non-compliance  \*\*Non-compliance \*\*Potential serious breach  \*\*Refer to CCTU/SOP018 & R&D/SOP003. *Note that Type 1 non-compliances do not require a N/C form to be completed, but should still be recorded on the N/C log* |
| **CI Justification of categorisation:** |
| **CI name………………………..………. Signature………………………Date…………………………** |

|  |  |
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| **For coordinating centre use only:**  Date Coordinating Centre became aware of Non Compliance |  |
| Coordinating Centre Non-compliance No. |  |
| Current number of similar non-compliances at this site |  |

**Send a copy of CI reviewed form to the CCTU regulatory team**

**SPONSOR OVERSIGHT ASSESSMENT**

|  |  |
| --- | --- |
| **Date non-compliance report received by CCTU** |  |
| **Date of Regulatory Team Assessment** |  |
| **Categorisation of non-compliance** (*Tick relevant box):*  Type 2 Type 3  Reportable minor Reportable major non-compliance  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** |  |
| **ADDITIONAL COMMENTS (if any):** | |

**Note: The Regulatory Team categorisation is the definitive categorisation for the purposes of escalation**

**Original Initial Sponsor oversight assessment to be retained by Sponsor, 1 copy to be sent to trial Coordinator**

**Date copy returned to trials team by the regulatory team \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date copy returned to the site team by the coordination team \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**