**Non Compliance Form**

**Trial Details**

|  |  |  |
| --- | --- | --- |
| **Chief Investigator:** |  | **Central** **Non-Compliance No.** |
| **IRAS Project ID:** |  | **for coordinating team** |
| **Trial Name:** |  |  |

**Site-Specific Details**

|  |  |  |
| --- | --- | --- |
| **Site Name /** **Site ID:** |  | **Local Non-Compliance No.** |
| **Principal Investigator:** |  |  |
| **Report Type** | Initial |  | Follow-Up |  |  |

**Category of Non-Compliance:**

***Please tick all that apply and enter the full details in the description of non-compliance box below***

|  |
| --- |
| **Informed Consent** *eg. Wrong version of consent form used, consenter and consentee signed on different days etc.* |[ ]
| **Inclusion / Exclusion Criteria** |[ ]
| **IMP** *eg. Expired IMP, wrong dose, wrong route of administration etc.* |[ ]
| **Trial Procedures / Assessments(please specify)\*** |  |
| **Missed or delayed safety assessment /missed visit\*** |[ ]
| **Missed or delayed research assessment /missed visit\*** |[ ]
| **Incorrect assessment performed** |[ ]
| **Samples***eg Samples mis-labelled, sample incorrectly collected, sample lost etc.* |[ ]
| **Privacy and Data Protection** |[ ]
| **Delayed reporting***eg. SUSAR, Potential Serious Breach etc.* |[ ]
| **Incorrect version of trial documentation** *eg. Patient ID card, GP letter, Protocol etc.* |[ ]
| **Staffing and training** *eg.**Not on delegation log, not trained in trial procedures etc.* |[ ]
| **Other, please specify**  |[ ]

*\* If a missed or delayed assessment/visit includes a missed safety assessment record as missed/delayed safety assessment. If it did not include a safety assessment record as missed/delayed research assessment*

**Details of Non-Compliance:**

|  |  |
| --- | --- |
| **Trial ID Number(s):** | *N/A if not applicable* |
| **Description of Non-Compliance** |
|  |
| **Date of Occurrence:** |  |
| **Date of site awareness:** |  |
| **Corrective Action:** |
| *Document here how the non-compliance was corrected.* *If it isn’t possible to correct the issue (eg in the event of incorrect consent in a now deceased patient) explain this in full.* |
| **Preventative Action:** |
| *Preventative actions are designed to stop this issue occurring again in the future. These should be considered at a site and a central/trial level. Consider the true root-cause of the issue.**Re-training is not a sufficient PA on its own.**Additional PA’s can and should be added by the central trial team as appropriate* * *Consider if trial documentation and processes really are clear for the user.*
* *Consider whether processes can be simplified – removing steps which add no value yet cause consistent non-compliances?*
* *Consider how documentation is used, would another document/form/manual be appropriate*
	+ *Would an additional document at a site level help align trial processes better?*
* *Consider all stages of the trial, is it a trial design issue which can’t be amended for this trial but could impact on future trial designs – these PA’s should still be recorded*
* *Be specific about which documents should be updated or created*
 |
| **Completed by:** *Enter details for person who completed form* | **Print name:** | **Trial Role:** | **Signature & Date:** |
|  |  |  |
| **PI Review\* or delegate as appropriate** |  |  |  |

*\*Where the PI & CI are the same person, please complete and sign the CI Review only.*

**Chief Investigator Review:**

|  |  |
| --- | --- |
| **Comments:** |  |
| **Signature & Date:** |  |

**Sponsor Representative Review:**

|  |  |
| --- | --- |
| **Date Initial Form Received by CCTU:** |  |
| **Name of Reviewer:** |  |
| **Date of Initial Review:** |  |
| **Is the CAPA above appropriate?** | **Yes** [ ]  **No** [ ]  |
| **If no, please state reasons why:** |  |
| **Follow-up action(s) required:** |  |
| **Is this a potential serious breach requiring escalation?**  | **Yes** [ ]  **No** [ ]  |
| **Non-Compliance Category** |  **T1 T2 T3****(minor)** [ ]  **(Major)** [ ]  **(Potential Serious Breach)** [ ]  |

**Sponsor Representative Impact Assessment:**

To be completely by the CCTU Regulatory Team only.

|  |  |
| --- | --- |
| **Further dissemination to participating sites within this trial required?***(Trial Team to action)* | **Yes** [ ]  **No** [ ]  |
| **Relevant for other Sponsored trials?** *(Regulatory Team to action)* | **Yes** [ ]  **No** [ ]  |
| **Sponsor Representative Comments:** |  |
| **Notification to CCTU QA Manager for inclusion on the Learning Log?***(Regulatory Team to action)* | **Yes** [ ]  **No** [ ]  |

**Sponsor Representative Sign-Off:**

|  |  |
| --- | --- |
| **Signature:** |  |
| **Date:** |  |

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