**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**