Please refer to the non-compliance examples table in section/appendix number of the protocol/Trial Procedures Manual/Monitoring Plan prior to completing this form

**Site-Specific Details**

|  |  |  |
| --- | --- | --- |
| **Site Name /** **Site ID:** |  | **Local Non-Compliance No.*****(Remember to add the NC to the local NC log)*** |
| **Principal Investigator:** |  |  |
| **Report Type** | Initial |[ ]  Follow-Up |[ ]   |

**Category of Non-Compliance:**

***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 consented 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:**

**Orange text is guidance and should be removed before the form is submitted for review**

|  |  |
| --- | --- |
| **Participant ID Number(s):** | N/A if not applicable |
| **Non-Compliance Details** |
| Include here:* Describe full details of the non-compliance in chronological order including dates
* Try not to use individuals’ names and refer to roles instead
* Do not include participant identifiable data – eg names/addresses etc
* Start from the beginning of the issue – explain it as a concise and clearly worded story that will be understandable to someone who is unfamiliar with the situation and staff involved
* Ensure that the main issue is clear and all pertinent details are included, for example
	+ visit dates and visit type (21/03/2025 – Day 1 visit)
	+ in open label trials include the treatment arm if applicable to the NC – do not unblind a patient unless this is required.
	+ length of delay outside of trial visit window
	+ if an assessment is missed is this for safety or primary endpoint (eg missed safety bloods)
	+ if multiple participants are involved in different stages of the NC, ensure each participants pathway is clear.
 |
| **Date of Occurrence:** |  |
| **Date of site awareness:** |  |
| **Corrective Action:** |
| Document here how the non-compliance listed above was corrected. Ideally present this in a bulleted list. Include the date that each action was completed – in most cases this is expected to be immediately following the identification of the non-compliance. If the action is still to be completed at the time of writing this report include a timeline and responsible party for implementation – for example this can relate to documentation updates or ongoing patient monitoring for safety reasons.If it isn’t possible to correct the issue (eg in the event of incorrect consent from a now deceased patient) explain this in full.There should be no new information which describes the non-compliance in this section, these details need to be included in the ‘Details’ section above. |
| **Non-Compliance Root Cause(s)** |
| Include here the root causes of the non-compliance – there can be multiple reasons as to why a non-compliance has occurred. If an investigation was performed, include details of when this was performed, by which roles and the outcomes.Please note, very rarely is ‘human error’ the actual root cause, and generally will not be accepted by the Sponsor. When identifying the actual root causes consider the documentation used during and in the lead up to the non-compliance, design of forms/documents, the environment in which the non-compliance occurred, resource concerns, accessibility to systems and documentation, support information available, location of the non-compliance etc.In order to support a root cause of human error all other considerations above need to have been ruled out and documented as such in this NC form. |
| **Preventative Action:** |
| Preventative actions are designed to stop this issue occurring again in the future and need to address the root causes identified above. These should be considered at a site and a central/trial level. . Ideally present this in a bulleted listRe-training is not a sufficient preventive action 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
* Provide a timeline and responsible party for implementation of each action

There should be no new information which describes the non-compliance in this section, these details need to be included in the ‘Details’ section above. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Completed by:** *Person who completed form* | **Print name:** | **Trial Role:** | **Signature & Date:** |
|  |  |  |
| **PI Review\*** **or delegate as appropriate** |  |  |  |

**Sponsor Representative Review:**

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

**Sponsor Representative Sign-Off:**

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

**Original Initial Sponsor Rep Review section for retention by the Sponsor, 1 copy to be sent to Trial Coordinator**

This section will be completed and retained by the CCTU Regulatory Team only. The Regulatory team will follow up any actions separately and file the relevant correspondence in the sponsor file.

**Sponsor Representative Impact Assessment:**

|  |  |
| --- | --- |
| **Further dissemination to participating sites within this trial required.***(Trial Team to action)* | **Yes** [ ]  **No** [ ]  |
| **Immediate Escalation to CI 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:** |  |