

**Non-Compliance Report Form**

Clinical Trials

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| **Document Reference ID:** | Noclor/Spon/T05/01 |
| **Effective Date:** | 1st March 2016 |

**Version History**

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| --- | --- | --- |
| Template ID | Version, Effective Date | Reason for Change |
| Noclor Template\_05 | 23/03/2015 |  |
| Noclor/Spon/T05/01 | Version 1, 01/03/2016 | New numbering system adopted for Noclor SOPs and associated documents (applicable to all Noclor partner NHS Trusts). This template has been assigned first version. |

**Scope of Use**

This Non-Compliance Report Form template must be used to report all protocol violations and non-compliance to protocol and GCP in accordance with SOP Noclor/Spon/S10/01.

**Specific Instructions for use**

Please insert sponsor email address at the bottom of the form. Page numbers (page x of y format) should be inserted in the footer of every page.

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**NON-COMPLIANCE REPORT FORM**

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| --- | --- | --- | --- |
| Trial Title |  | | |
| EudraCT number: |  | IRAS Ref |  |
| Investigator Name: |  | Site Name/Ref: |  |
| Sponsor Protocol Ref: |  | Sponsor: |  |
| **All protocol violations and non-compliances to trial procedures, sponsor procedures or GCP must be reported to the sponsor by submitting this Non-Compliance Report Form within 24 hours of becoming aware of the event.**   |  |  |  |  | | --- | --- | --- | --- | | Which category of deviation/non-compliance is being reported? Please tick most relevant box. | Protocol Violation  Non-Compliance to study or sponsor procedures/SOPs  Non-Compliance to GCP | | | | Date Violation/Non-Compliance Occurred | **//**  Day/month/year | Date Local Investigator was informed/became aware of event | **//**  Day/month/year | | Description of violation/non-compliance (include participant study numbers, how it was identified, who it was reported to): |  | | | | Significance of violation/non-compliance to Subject Safety (as assessed by Investigator): |  | | | | Significance of Deviation to Integrity of Data (as assessed by Investigator): |  | | | | Corrective action (if applicable): |  | | | | Preventative action (if applicable): |  | | |   **Reported by:**   |  |  |  |  | | --- | --- | --- | --- | | Print Name: |  | Signature | **//**  Day/month/year | | Job Title/Role on Trial |  | | Reviewed by Investigator (CI/PI as relevant) : | Print Name | Signature | **//**  Day/month/year |   **Please submit completed and signed form by email to the Sponsor: <<insert sponsor email address>>. File a copy of this report with the CRF (if participant specific report) and in the ISF/ TMF.** | | | | | |

**For Sponsor Use only:**

|  |  |  |
| --- | --- | --- |
| **Date report received:** |  | |
| **Seriousness** | Did not require reporting to sponsor (add comment to justify )  Minor deviation/non-compliance  Major deviation/non-compliance  USM  Serious Breach  *Serious breach defined as a breach likely to effect to a significant degree:*  *the safety or physical or mental integrity of the subjects of the trial; or*  *the scientific value of the trial* | |
| **Comments:** |  | |
| **Further reporting/escalation required:** |  | |
| **Further corrective action (if required)** |  | |
| **Further preventative Action (if appropriate)** |  | |
| **Status:** | On-going | Date of next review: //  Day/month/year |
| Closed | Date: //  Day/month/year |

**Reviewed by:**

|  |  |
| --- | --- |
| **Name:** |  |
| **Job title:** |  |
| **Signature:** |  |
| **Date:** | **//** Day/month/year |