

**Protocol Deviations, Violations & Non-Compliance to GCP Log**

Clinical Trials

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| **Document Reference ID:** | Noclor/Spon/T04/01 |
| **Effective Date:** | 1st March 2016 |

**Version History**

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| Template ID | Version, Effective Date | Reason for Change |
| Noclor Template\_04 | 23/03/2015 |  |
| Noclor/Spon/T04/01 | 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 Protocol Deviations, Violations & Non-Compliance to GCP Log template must be used to record all protocol deviations, violations and non-compliances to protocol /GCP at investigator sites in accordance with SOP Noclor/Spon/S10/01.

**Specific Instructions for use**

The trial specific short title and EudraCT reference (for CTIMPs) or IRAS reference (for non-CTIMPs) should be inserted in the header of all pages of this log. The table header row should be inserted at the top of each new page.

Page numbers (page x of y format) and date last printed should be inserted in the footer of every page.

**PROTOCOL DEVIATIONS, VIOLATIONS & NON-COMPLIANCE TO GCP LOG**

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| **Trial Title** | |  | | | | | | | | | | |
| **EudraCT number (CTIMPs)** | |  | | | **IRAS Ref:** | | | |  | | | |
| **Investigator (CI/PI):** | |  | | | **Site Ref:** | | | |  | | | |
| **Protocol Ref:** | |  | | | **Sponsor:** | | | |  | | | |
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| All departures from the protocol , study/sponsor procedures or non-compliance to GCP must be recorded on this log and reported as instructed.  Categories  **Protocol Deviation** - Unintended (non-serious) departures from the approved protocol (an example would be a study visit date being outside the window defined in the protocol). These should be recorded in real time (i.e at the time departure identified) on this log as **Category 1**. This log will be reviewed at monitoring visits and may be requested by sponsor/study team at intervals during the trial.  **Protocol violation** (**Category 2**) or **Non-compliance** (**Category 3**) is any deviation from the protocol, study or sponsor procedures and or GCP that is not approved by the sponsor/REC/MHRA prior to its implementation.  These events should be recorded on this log and reported to the sponsor by submitting a Non-Compliance Report Form (Noclor/Spon/T05/0X) within 24 hours of becoming aware of the event.  An **Urgent Safety Measure (USM)** is a procedure which is not defined by the protocol that is be put in place with immediate effect without prior authorisation by the REC and MHRA in order to protect the trial participants from any immediate hazard to their health and safety. If an USM is instigated at site the Principal Investigator must contact the Chief Investigator immediately and record details of the USM here as **Category 4**. | | | | | | | | | | | | |
| **Description of deviation /violation/non-compliance (include participant study number where relevant)** | | **Date Occurred** | | **Date Investigator informed (Investigator should sign and date each entry)** | **Category –Please tick appropriate box as defined above** | | | | | **Actions taken by Local Investigator** | | **Date sponsor notified** | | |
| **1** | | **2** | **3** | **4** | **Corrective** | **Preventative** |
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