**SOP Deviation Form**

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| **Document Reference ID:** | Noclor/Inter/T12/01 |
| **Effective Date:** | 15th February 2016 |

**Version History**

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| --- | --- | --- |
| Template ID | Version, Effective Date | Reason for Change |
| SOP CA001 Appendix 12 | Version 1, 14/04/2009 | First version |
| SOP CA001 Appendix 12 | Version 2, 18/11/2012 | Version change to reflect revision to SOP CA001 |
| Noclor/Inter/T12/01 | Version 1, 15/02/2016 | New numbering system adopted for Noclor SOPs and associated documents (applicable to all Noclor partner NHS Trusts). This template has been assigned first version. Template deviation form has been revised to reflect procedures detailed in SOP Noclor/Inter/S01/01 and Sponsor SOPs. |

**Scope of Use**

This form should be completed by the Chief Investigator/ Sponsor Representative for planned deviations from Sponsor SOPs. The completed form should be filed with the master SOP (in the SOP Master File) and a copy retained in the relevant Study/Trial Master Files (S/TMFs)

Insert page numbers (Page X of Y) in the footer of completed form.

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| **SOP Title:** |  | | |
| **SOP Reference ID:** |  | **Effective Date:** |  |

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| **Planned deviation from above SOP:** | | | | |
| |  |  |  |  | | --- | --- | --- | --- | | Study Title: |  | | | | EudraCT Ref (if CTIMP) or IRAS Ref : |  | Sponsor : |  |   **Add specific deviation details below :** | | | | |
| **Corrective Action and Preventative Action (CAPA)** | | | | |
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| **Signatures** | | | | |
| **By signing this form the Chief Investigator acknowledges the details of the SOP Deviation and confirms appropriate action has been taken.** | | | | |
| **Chief Investigator** | Print Name |  | | |
| Signature | | **Date:** |  |
| **Sponsor Representative** | Name |  | | |
| Signature | | **Date:** |  |

**This SOP Deviation Form must be filed with the Master SOP in the SOP Master File and a copy retained in the relevant Study/Trial Master File(s) (S/TMFs).**