

**Amendment Log**

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| **Document Reference ID:** | Noclor/Spon/T06/02 |
| **Effective Date:** | 15th June 2016 |

**Version History**

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| Template ID | Version, Effective Date | Reason for Change |
| Noclor Template\_06 | 23/03/2015 |  |
| Noclor/Spon/T06/01 | 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. Minor revisions to previous version. |
| Noclor/Spon/T06/02 | Version 2, 15/06/2016 | Minor revisions further to full implementation of HRA Approval Systems (NHS permissions) |

**Scope of Use**

This Amendment Log template should be used for research studies sponsored by a Noclor NHS Partner Trust to document initially approved documents and subsequent changes to the study post-approval in accordance with SOP Noclor/Spon/S07/02.

**Specific Instructions for use**

The research 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 should be inserted (page x of y format) in the footer of every page. Date documented printed (where copy placed on file) should appear in footer.

**AMENDMENT LOG**

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| **Research Title** |  | | |
| **Chief Investigator:** |  | | |
| **Sponsor Protocol Ref:** |  | **Sponsor Name :** |  |
| **EudraCT No (for CTIMPs):** |  | **REC Ref:** |  |
| **IRAS Ref:** |  | **NIHR Portfolio Study :** | YesNo |

**PART A- INITIAL APPROVALS**

Please only include details of the documents/versions approved initially by the REC and other regulatory bodies (as appropriate). Amendments to any these approved documents (or the addition of new documents requiring approval) post-initial approval should be detailed in Part B of this form.

| **Study Document**  **List all documents as per the initial submission checklist/approval letters.**  **If different versions of the same document have been approved initially by different bodies please add rows and details of versions as relevant (should tie in with Part B if amendment notifications were required to other bodies).** | **Version/Date** | **Check all appropriate boxes as relevant for document version/date** | | | | |
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| **REC** | **MHRA** | **HRA** | **Other Approval Body (specify and attach additional table if required)** | |
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**PART B – AMENDMENTS**

In addition to the table below please complete NHS/R&D Substantial Amendment Approval /Implementation Log Noclor/Spon/T13/0X for all substantial amendments made subsequent to initial HRA approval of the study

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| **Amendment**  **Code/Number** | **Classification (as confirmed by sponsor)** | | **Brief Description/ Purpose of Amendment** | **Amendment Category A/B/C** | **Details of Documents Submitted**  **Version Number and Date (dd/mm/yyyy)** | | **Bodies the amendment has been notified to (check all boxes as appropriate)** | **Approval/Implementation Date (substantial amendments)**  **Approval/ Acknowledgement Date (non-substantial amendment/minor clarifications)**  **Day/Month/Year** |
| **Substantial** | **Non Substantial/**  **Minor Clarification** | **New** | **Revised** |
|  |  |  |  |  |  |  | REC | // |
| MHRA | // |
| HRA | // |
| Other (specify) | // |
|  |  |  |  |  |  |  | REC | // |
| MHRA | // |
| HRA | // |
| Other (specify) | // |