

**NHS/R&D Substantial Amendment Approval /Implementation Log**

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| **Document Reference ID:** | Noclor/Spon/T13/02 |
| **Effective Date:** | 15th June 2016 |

**Version History**

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| Template ID | Version, Effective Date | Reason for Change |
| Noclor/Spon/T13/01 | Version 1, 01/03/2016 |  |
| Noclor/Spon/T13/02 | Version 2, 15/06/2016 | Minor revisions further to full implementation of HRA Approval Systems (NHS permissions) |

**Scope of Use**

This NHS/R&D Substantial Amendment Approval /Implementation Log template should be used for research studies sponsored by a Noclor NHS Partner Trust to document approval or presumed ongoing permission at participating NHS sites in regards to implementation of substantial amendments 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.

**NHS/R&D SUBSTANTIAL AMENDMENT APPROVAL /IMPLEMENTATION LOG**

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| **Research Title** |  | | |
| **Chief Investigator:** |  | | |
| **Sponsor Protocol Ref:** |  | **Sponsor Name :** |  |
| **EudraCT No (for CTIMPs):** |  | **IRAS Ref:** |  |

**Please complete the table for all substantial amendments made to the trial further to the initial HRA approval**

**The amendment code should tie in with the details added to amendment log Noclor/Spon/T06/02.**

**For each participating NHS site please add details to the table regarding their status for each substantial amendment as either:**

* the date of approval (where written communication of no objection to implementation has been provided directly from the NHS organisation and is evident on file)

OR

* date of presumed permission (this should be 35 days from when the site was notified of the amendment by the CI, where other regulatory approvals are in place and where written communication of approval or objection has not been provided from the NHS organisation).

OR

* Where a substantial amendment is not required to be considered by a specific site please specify which site(s) the substantial amendment is not applicable too by checking the n/a box

| **Amendment Code** | **Category of substantial amendment A/B/C** | **Site Name/NHS Trust (list all participating NHS research sites)** | **Amendment N/A to Site** | **Date amendment notified to site** | **Date of approval (confirmed)**  **Day/Mth/Yr** | **Date Presumed Permission**  **Day/Mth/Yr** |
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