**Site Initiation Report**

Clinical Trials

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| --- | --- |
| **Document Reference ID:** | Noclor/Spon/T08/01 |
| **Effective Date:** | 23rd February 2016 |

**Version History**

|  |  |  |
| --- | --- | --- |
| Template ID | Version, Effective Date | Reason for Change |
| SOP CA012 Appendix 1 | Version 1, 14/04/2009 | First version |
| SOP CA012 Appendix 1 | Version 2, 18/11/2012 | Version change to reflect revision to SOP CA012 |
| Noclor/Spon/T08/01 | Version 1, 23/02/2016 | 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 report has been revised to reflect procedures detailed in SOP Noclor/Spon/S05/01. |

**Scope of Use**

This Site Initiation Report template should be used in accordance with SOP Site Initiation and Activation (Clinical Trials) Noclor/Spon/S05/01.

Insert trial reference details (EudraCT ref for CTIMPs and IRAS ref for non-CTIMPs), site name or reference and the date of site initiation in the header of every page and page numbers (X of Y format) in the footer of every page.

|  |  |  |  |
| --- | --- | --- | --- |
| **Trial Name:** |  | | |
| **Sponsor:** |  | **Principal Investigator:** |  |
| **IRAS Ref :** |  |
| **EudraCT Number (CTIMPs):** |  | **Site Initiation Date:** |  |
| **Site (No):** |  | **Site Name and Address:** |  |
| **Type of site initiation :** | Site Visit  Investigator Meeting  Video or teleconference  Other, please specify…………………………………………. | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Study Team/Sponsor personnel present/involved (name and role):** | | | |
|  | | | |
| **Site personnel present/involved** (full names and study role of personnel listed here should correspond to the completed Site Initiation /Monitor Log Noclor/Spon/T09/01): | | | |
|  | | | |
| **Site Initiation/Monitor Log (Noclor/Spon/T09/01) Completed and Copy Collected for TMF** | | **Yes** | **No** |
|  | | | |
| **Please list all specific documents / materials that were referred to during site initiation and whether they were provided to the site in advance of or supplied at the time of the initiation**   |  |  |  |  | | --- | --- | --- | --- | | Document /Material Referred to during site initiation (for documents provide document title and document reference) | Version/Date  (documents only) | Provided to site | | | In advance of initiation | At the time of initiation | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  |   **\***Insert more rows as required | | | |
| Please indicate whether the points in each Section 1-4 were discussed at site initiation. There should be a response to each point (Yes, No or Not Applicable (NA)). Add comments on any discussions /actions arising in each section as appropriate.   1. **Protocol and Study Procedures** | | |

|  |  | **Yes** |  | **No** |  | **N/A** |
| --- | --- | --- | --- | --- | --- | --- |
| 1.1 | Aims and objectives of the study |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.2 | Study design |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.3 | Subject inclusion/exclusion criteria |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.4 | Prohibited medication |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.5 | Informed Consent procedure |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.6 | Medical Assessment/Confirmation of Eligibility |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.7 | Study procedures and assessment schedule |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.8 | IMP instructions, accountability and compliance |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.9 | Randomisation and code breaking procedures |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.10 | Reference Safety Information (and updates) |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.11 | Adverse Event reporting |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.12 | Stopping Rules |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.13 | Pregnancy Reporting and follow-up |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.14 | Urgent Safety Measures |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.15 | Protocol Deviations and non-compliance |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.16 | Monitoring Plan |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.17 | Audit and Inspection |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.18 | Testing and training of IVRS, eCRFs (other electronic web-based systems as relevant) |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.19 | Start and end dates for study and enrolment rate |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.20 | End of study notification and close-out |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 1.21 | Publication Policy |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **Comments on relevant discussions /actions arising :** | | | | | | |

1. **Documentation**

|  |  | **Yes** |  | **No** |  | **N/A** |
| --- | --- | --- | --- | --- | --- | --- |
| 2.1 | Was the Investigator Site File (ISF) setup by co-ordinating study team to sponsor template (Noclor/Sponsor/T03) and supplied to the site |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.2 | Written confirmation from Competent Authority that the study can proceed present in ISF? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.3 | Ethics committee approval present in ISF (including composition and constitution)? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.4 | Fully executed clinical trial agreement for site (between sponsor and site organisation) present in ISF? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.5 | Site permission/local approval present in ISF? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.6 | Indemnity/insurance documentation present in ISF (as relevant to site if non-NHS)? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.7 | Protocol PI signature page completed (protocol version should be clear on signature page).  Insert Protocol Version ……………………….. |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.8 | PI signature page collected for TMF and filed in ISF? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.9 | ISF content, maintenance and storage discussed? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.10 | Study specific procedures/manuals discussed? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.11 | Local versions of PIS, consent, GP letters etc |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.12 | Reviewed screening/ enrolment logs and discussed how these should be completed |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.13 | CRFs completion and storage  Insert version of CRF reviewed……………….. |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.14 | Discussed completion of Adverse Event Logs/Forms and SAE report forms |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.15 | Reviewed forms for recording protocol deviations and reporting non-compliance |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.16 | Version Control – Document Inventory Log |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.17 | Amendments (procedures for implementation) and Amendment Logs |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.18 | Data management and handling data queries |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.19 | Source data requirements and location discussed and source data location log completed (as relevant to site) |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2.20 | Archiving of documents |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **Comments on relevant discussions /actions arising :** | | | | | | |

1. **Staff and facilities**

|  |  | **Yes** |  | **No** |  | **N/A** |
| --- | --- | --- | --- | --- | --- | --- |
| 3.1 | ICH-GCP and PI responsibilities on study were discussed with PI? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3.2 | Is the Principal Investigator appropriately qualified and trained to conduct the study?  *CTIMPs, please comment below if this is the first CTIMP the PI is being PI on and how many CTIMPs the PI is currently working on as PI?* |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3.3 | Current CV of PI (signed and dated) and GCP certificate collected for the TMF |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3.4 | Delegation of roles and responsibilities to members of the study team and evidencing ‘appropriate’ expertise and training in ISF discussed? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3.5 | Is there dedicated research staff support to this study (e.g a research nurse).  If yes, please name ………………………… |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3.6 | Delegation of Authority & Signature Log completed for those present at site initiation and copy collected for the TMF?  *For CTIMPs, where members of the site study team are not present at site initiation visit (and therefore not signed onto the delegation log) their details should be added to the table 3.16* |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3.7 | CVs and relevant and/or study specific training records for members of team (as they appear on the delegation log) filed in the ISF |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3.8 | Are there any conflicting studies at site? If yes please add details in comment section |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3.9 | Access and existence of suitable subjects for the trial (i.e feasibility of recruitment).  Please insert agreed recruitment target for site ………………….. |  |  |  |  |  |
| 3.10 | Continuing suitability of site clinical facilities (sufficient time and resources). Please add comments as appropriate if any changes planned for future that may affect trial at the site. |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3.11 | Suitable facilities for storage and security of study documents (ISFs, CRFs etc) |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3.12 | Laboratory procedures and or manual reviewed? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3.13 | Sample handling preparation and storage areas available and adequate for the study purpose? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3.14 | Site equipment assessed and confirmed as fit for purpose including review of maintenance records (e.g centrifuges, freezers)? List all equipment to be used in comments section |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3.15 | Laboratory reference ranges obtained? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3.16 | Please list all site staff that will be involved in the study, but who were not present at the site initiation (and not signed onto the delegation log). Indicate the planned start date, role on study and method these staff will be trained (e.g. by Principal Investigator etc). | | | | | |
| |  |  |  |  | | --- | --- | --- | --- | | Full Name | Planned Start Date (approx.) | Roles and Responsibilities | Method of Training | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  |   \*Insert more rows as required | | | | | | |
| **Comments on relevant discussions /actions arising :** | | | | | | |

1. **Pharmacy (this section is relevant to CTIMPs only)**

|  |  | **Yes** |  | **No** |  | **N/A** |
| --- | --- | --- | --- | --- | --- | --- |
| 4.1 | Is there a study/site specific pharmacy agreement in place? For example, where a different NHS Trust to the site NHS Trust provides the pharmacy services |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 4.2 | Was IMP supplied to site in advance of the site initiation visit?  If no, please comment as to why IMP was not supplied in advance of visit and whether a separate visit to site is planned once IMP is supplied to the site. If a further visit is not planned please provide justification as to why this is not required. |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 4.3 | Was a separate visit to Pharmacy conducted?  If no, please comment as to whether separate visit planned. |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 4.4 | Will IMP be stored, dispensed and accounted for outside of the main pharmacy (i.e IMP transferred to site for storage, dispensing and completion of IMP accountability forms) rather than direct from pharmacy?  If yes, please comment as to whether the site pharmacy has systems in place to oversee and monitor the out of pharmacy IMP handling and management activities |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 4.5 | Are IMP storage facilities adequate and appropriate for the study? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 4.6 | Were relevant details relating to the IMP storage (temperature monitoring/excursions) handling/dispensing/returns discussed? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 4.7 | Accountability forms/logs reviewed? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 4.8 | Were the IMP supplies checked? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 4.9 | Destruction of IMP discussed? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 4.10 | Was the site pharmacy provided with Pharmacy Site File (PSF) prepared by study team? If no please add comment as to what PSF setup was agreed with the site. |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 4.11 | Was PSF content, maintenance and archive discussed? |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **Comments on relevant discussions /actions arising :** | | | | | | |

1. **Please list all documents collected at site initiation (any documents outstanding should be added to the actions arising 7.)**

|  |  |  |
| --- | --- | --- |
| Details of Document Collected (document title and reference where relevant) | Version/Date  (if applicable) | Comments |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

\*Insert more rows as required

1. **Please add any general comments about the site initiation**

|  |
| --- |
|  |

1. **Actions arising from site initiation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Action Ref : | Action | Person Responsible | Date to be completed by: | Check box when action completed |
|  |  |  |  |  |
|  |  |  |  |  |
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1. **Signature (of person who has completed this site initiation report)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name:** |  | | |
| **Signature:** |  | **Date:** |  |

1. **Sponsor Review and Study Activation Notification**

|  |  |  |  |
| --- | --- | --- | --- |
| **Date site initiation report received :** | | |  |
| **Sponsor comments on review of report:** |  | | |
| **Name of Reviewer:** |  | **Job Title of Reviewer:** |  |
| **Signature:** |  | **Date:** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **STUDY ACTIVATION NOTICE**  **The site named below is authorised by sponsor to commence the study** | | | | |
| **Short study title :** | |  | **EudraCT Ref** |  |
| **IRAS Ref** |  |
| **Site** | **Number:** |  | **Principal Investigator Name:** |  |
| **Name:** |  |
| **Sponsor Representative Signature :** | |  | **Date of Issue:** |  |

**The signed report and study activation notice should be filed in the Trial Master File (Site File) and a copy filed in the Investigator Site File (ISF).**