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| --- |
| **Research Project Title (short or acronym):**  |
| **Chief Investigator:**  |
| **Sponsor Reference:**  | **REC reference:**  | **EudraCT No (if a CTIMP):** |
| **Site Name:**  | **Principal Investigator at site:** |
| **Date of initiation meeting:** | **Attendees:**See Initiation Attendance Log |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Document / activity** | **Yes** | **No** | **NA** | **Comments** |
| **Research project procedures** |
| 1. Staff familiar with the protocol
 |  |  |  |  |
| 1. Staff familiar with consent
 |  |  |  |  |
| 1. Staff familiar with the randomisation
 |  |  |  |  |
| 1. Staff familiar with the data collection
 |  |  |  |  |
| 1. Staff familiar with safety reporting
 |  |  |  |  |
| 1. Adequate study staff are available
 |  |  |  |  |
| 1. Assign responsibilities of the staff in the site project team (using delegation log)
 |  |  |  |  |
| 1. Process for training new staff in place
 |  |  |  |  |
| 1. [xxx] department agree to support the research project
 |  |  |  |  |
| 1. Check that any other relevant facilities that are required are available and functional
 |  |  |  |  |
| 1. Train on management of ISF
 |  |  |  |  |
| 1. Database training
 |  |  |  |  |
| 1. [any other bespoke requirements to be discussed e.g. pharmacy, laboratories, equipment]
 |  |  |  |  |
| **ISF contents check:** |
| 1. Clinical trial agreement (CTA) signed by site and sponsor
 |  |  |  |  |
| 1. REC approval letter
 |  |  |  |  |
| 1. R&D approval letter
 |  |  |  |  |
| 1. Completed delegation log
 |  |  |  |  |
| 1. Competed training log
 |  |  |  |  |
| 1. CVs for staff on delegation log
 |  |  |  |  |
| 1. GCP certificates for staff on delegation log
 |  |  |  |  |
| 1. Site-specific participant documents
 |  |  |  |  |
| 1. Blank CRFs
 |  |  |  |  |
| 1. Handbooks (if required)
 |  |  |  |  |

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| 1. [any other ISF documents specific to the research project e.g pharmacy, laboratories, equipment]
 |  |  |  |  |

**Please record any relevant notes about the initiation here**

**Decision following initiation meeting:**

|  |  |
| --- | --- |
|  | Site ready to be activated  |
|  | Minor actions required – site can be activated whilst they are completed  |
|  | At least one major action required – site cannot be activated until completed |
|  | Site unable to comply with research project requirements and will not be activated  |

**Please record the details of any actions required and the date that they were completed**

(this can be retrospectively completed if only minor actions were noted):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Action ID**  | **Details** | **Action type (minor/major)** | **Action Owner** | **Date completion required** | **Date completed** |
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**Once major actions have been completed satisfactorily, the site can be approved for activation by completing the table below.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Title** | **Name** | **Signature** | **Date** |
| Chief Investigator |  |  |  |
| Trial Manager |  |  |  |
| Principal Investigator |  |  |  |