|  |  |  |  |
| --- | --- | --- | --- |
| **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) |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**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 |  |  |  |