**Site Activation Checklist**

**Study Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Sponsor (IRAS) Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Site Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Site Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |
| --- | --- | --- | --- |
| **Task**  | **Yes** | **No** | **N/A** |
| Confirmation of sponsorship including permission to activate sites received from JRMO (site activation cannot begin until this has been received) |  |  |  |
| Site capacity and capability received in writing  |  |  |  |
| Key Study staff (PI, Research Nurse etc.) initiated  |  |  |  |
| Site initiation report sent to site, PI, CI, site pharmacy, monitor and all actions complete |  |  |  |
| Site delegation log completed and a copy received by coordinator. |  |  |  |
| Pharmacy staff initiated and all outstanding actions completed |  |  |  |
| Any other relevant departments (e.g. imaging) initiated and all outstanding actions completed |  |  |  |
| Investigator site file at site, complete in accordance with “ISF checklist” (JRMO SOP 45 Associated Document 6&7) |  |  |  |
| Pharmacy File at site, complete and in accordance with “Pharmacy Site File checklist” (JRMO SOP 45 Associated Document 8) |  |  |  |
| All study supplies at site (i.e.: CRFs, lab kits, CDs, devices etc.)  |  |  |  |
| All site documents present in TMF:* Copy of site capability and capacity
* Copy of contract/s (if applicable)
* CVs for site staff
* Copy of signed delegation log
* Copy of completed training log
* Local lab documentation (if applicable)
* Source data location list

Documentation in site electronic systems |  |  |  |
| Electronic accounts set up, tested (this must be documented) and activated (eCRF, randomisation, IMP ordering etc.) ( if applicable) |  |  |  |
| Emergency / Out of hours contact details tested and documented  |  |  |  |
| IMP ordered/on site/process in place for site ordering (as per study protocol and IMP manual)**NB – IMP supply to sites can only be initiated once Site Approval or Capability and Capacity have been issued** |  |  |  |
| Adequate supply of investigational devices at site.  |  |  |  |

**Site Activated on: \_\_ \_\_ / \_\_ \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_**

**Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (CI or person delegated to activate sites)**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_ \_\_ / \_\_ \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_**