STUDY ACTIVATION CHECKLIST

*Complete and file with the study files prior to study activation*.

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| --- | --- |
| **Sponsor:** |  |
| **Protocol ID #:** |  |
| **Protocol Title:** |  |
| **Study Monitor Name:** |  |
| **Contact Information** | Tel:  E-mail:  Cell: |

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| **Required Documents Checklist** | | | | |
| Received or Filed at Site | | Date  ddmmmyy  (or N/A) | To Sponsor | Date  ddmmmyy  (or N/A) |
| ❑ | Notification of regulatory approval of protocol from sponsor |  |  |  |
| ❑ | CV of QI and copy of medical license |  | ❑ |  |
| ❑ | Signed QI Undertaking form |  | ❑ |  |
| ❑ | Signed FDA 1572 form (if applicable) |  | ❑ |  |
| ❑ | CVs of key site personnel |  | ❑ |  |
| ❑ | Signed protocol agreement page |  | ❑ |  |
| ❑ | Signed REB approval letter |  | ❑ |  |
| ❑ | REB approved consent form |  | ❑ |  |
| ❑ | REB attestation |  | ❑ |  |
| ❑ | REB composition |  | ❑ |  |
| ❑ | Signed Clinical Trial Agreement |  | ❑ |  |
| ❑ | Signed Budget |  | ❑ |  |
| ❑ | Financial Disclosures |  | ❑ |  |
| ❑ | Laboratory certification/accreditation In the absence of lab accreditation, provide CV of Lab Director. *Not required if using a central laboratory, as the sponsor will have copies of all this information in-house.* |  | ❑ |  |
| ❑ | Normal value(s)/range(s) for medical, laboratory or technical procedures or tests |  | ❑ |  |
| ❑ | Instructions for handling of investigational product(s) and trial-related materials |  | ❑ |  |
| ❑ | Shipping records for investigational product(s) and trial-related materials |  | ❑ |  |
| ❑ | Unblinding procedures, if trial is blinded |  | ❑ |  |

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| **Forms, Activities, Supplies** | | | |
| ❑ | Protocol summary sheets created | | |
| ❑ | Subject logs (recruitment, enrollment and follow-up) created | | |
| ❑ | Other study tools/forms created. Specify: | | |
| ❑ | Randomization/registration instructions available | | |
| ❑ | Staff Training on the protocol completed: | | |
|  | Department | Name | Date |
|  | Pharmacy |  |  |
|  |  |  |  |
|  | Nursing |  |  |
|  |  |  |  |
|  |  |  |  |
|  | Physicians/Fellows |  |  |
|  |  |  |  |
|  |  |  |  |
|  | Laboratory |  |  |
| ❑ | Investigational product received | | |
| ❑ | Laboratory supplies received | | |
| ❑ | Other sample supplies received | | |
| ❑ | CRFs received | | |
| ❑ | Other, specify: | | |

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| --- | --- | --- |
| Departmental Study Contacts | | |
|  | Name | Contact Information (phone, email) |
| QI |  |  |
| CRC |  |  |
| Pharmacy |  |  |
| Nursing |  |  |
| Laboratory |  |  |
| Pathology |  |  |
| Radiology |  |  |
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|  |  |  |  |  |
| Signature of Person Completing Form |  | Name |  | Date |