|  |  |
| --- | --- |
| **PROTOCOL IMPLEMENTATION CHECKLIST** | |
| **PI:** Click or tap here to enter text. | **Coordinator:** Click or tap here to enter text. |
| **Study Title:** Click or tap here to enter text. | |
| **Protocol Version:** Click or tap here to enter text. | **Sponsor:** Click or tap here to enter text. |
| **Date:** Click or tap to enter a date. |  |

|  |  |
| --- | --- |
| **1. Collect and Submit the Following Documents, as required** | |
| Signed Form FDA 1572 or Investigator’s Agreement | Executed Clinical Trial/Research Agreement |
| CVs and Medical Licenses *(if applicable)*, signed & dated | Final Budget |
| Laboratory Director’s CV, signed & dated | Center for Medicare authorization/approval |
| Completed Financial Disclosures/COI Form | Hospital Billing Account |
| CITI Training Completion Certificates | IRB Approval Letter |
| Protocol Signature Page, signed | IRB Letter of Assurance and IRB Roster Memo |
| Documentation of protocol-specific training of research team members listed on the Delegation of Authority Log | IRB-Approved ICF & HIPAA Authorization *(if applicable)* |
| Laboratory Certification and Range of Normal Values | IRB-Approved Marketing & Recruitment Materials |
| IND/IFU or IDE Submission (30 days post FDA receipt) | ClinicalTrials.gov registration |
| Investigator’s Brochure |  |

|  |
| --- |
| **2. Prepare the Following Protocol-Specific Documents, as required** |
| Study-Specific Worksheets  Subject Logs (screening, enrollment, follow-up)  Protocol Summary Sheets (purpose, inclusion/exclusion criteria)  Investigational Product Administration and Information Sheets (AEs, administration)  Special Lab Work Requisitions, if required by the institution |

|  |
| --- |
| **3. Confirm Inventory and Supplies, as required** |
| IP Supplies received  Laboratory Supplies received (central and/or hospital)  Case Report Forms received/created  Access to Electronic Data Capture System(s) granted |

|  |
| --- |
| **4. Schedule and Conduct Study Implementation Meeting, as required** |
| Confirm best day/time with PI  Send meeting invite to all research staff  Provide copies of currently approved documents  Provide agenda  Finalize Recruitment Plan  Complete Delegation of Authority Log  Develop list of outstanding items to follow up on after meeting |

|  |  |
| --- | --- |
| **5. Conduct Ancillary Staff In-Service & Training, as required** | |
| Clinical Team  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Nursing  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Pharmacy  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Laboratory  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Imaging  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Other  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| **6. Open Protocol to Accrual** |
| Once all outstanding items have been resolved,  Open Protocol to accrual  Announce the opening of the trial to all research staff |

|  |
| --- |
| **Signatures:** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *Form Completed By (print name & sign)*   *Date* |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *PI Signature* *(optional)*  *Date* |