|  |
| --- |
| **PROTOCOL IMPLEMENTATION CHECKLIST** |
| **Protocol:** |  | **PI:** |  | **Primary Coordinator:** |  |

|  |
| --- |
| 1. **Collect and submit the following documents (as required)**
 |
| [ ]  Signed Form FDA 1572 or Investigator’s Agreement [ ]  CVs of personnel listed on the Delegation of Authority Log and Medical Licenses (if applicable)[ ]  Financial Disclosures/Conflicts of Interest completed[ ]  Signed protocol signature page[ ]  Investigator’s Brochure [ ]  IRB approval letter including Partial HIPAA Authorization Waiver for screening[ ]  IRB letter of assurance and IRB roster[ ]  IRB approved ICF and/or HIPAA Authorization[ ]  IRB approved marketing and recruitment materials[ ]  Final budget | [ ]  Executed Clinical Trial Agreement (CTA) (OSP Project Number received) [ ]  Center for Medicare authorization/approval[ ]  IND/IFU or IDE Submission (30 days post FDA receipt)[ ]  ClinicalTrials.gov registration[ ]  Laboratory certification and range of normal values[ ]  Laboratory Director’s CV[ ]  IHIS research trial uploaded/Hospital billing account created[ ]  Documentation of protocol-specific training of research team members listed on the Delegation of Authority Log |
| 1. **Prepare the following protocol specific documents (if applicable)**
 |
| [ ]  Study-specific worksheets [ ]  Subject logs (screening, enrollment, and 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) |

|  |
| --- |
| 1. **Confirm the following inventory and supplies (if applicable)**
 |
| [ ]  IP Supplies received [ ]  Laboratory supplies (central and/or hospital) received [ ]  Case Report Forms received/created or access to Electronic Data Capture system(s) granted |
| 1. **Schedule and conduct study implementation meeting (if applicable)**
 |
| [ ]  Confirm best day/time with PI’s administrative assistant [ ]  Send meeting invite to all involved research staff[ ]  Provide copies of currently approved documents[ ]  Provide agenda[ ]  Finalize Recruitment Plan[ ]  Complete Delegation of Authority Log during meeting[ ]  Develop outstanding items list during meetings to follow up on after meeting |
| 1. **Conduct ancillary staff in-service & training (as appropriate)**
 |
| [ ]  Clinical Team\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Date) [ ]  Pharmacy \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Date)[ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Date) | [ ]  Nursing \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Date)[ ]  Laboratory \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Date)[ ]  Imaging \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Date) |
| 1. **Open protocol to accrual**
 |
| [ ]  Once all outstanding items have been resolved, open the protocol to accrual with note to all involved research staff announcing the opening of the trial |
| **Person Completing the Form:** |  |
| **Signature:** |  | **Date:** |  |