|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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  Financial Disclosures/Conflicts of Interest completed  Signed protocol signature page  Investigator’s Brochure  IRB approval letter  IRB letter of assurance  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  IRB approved Partial HIPAA Authorization Waiver for screening  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  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:** |  |