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| **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. |  |

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| **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 |  |

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| **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 |

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| **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 |

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| **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  |

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

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| **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  |

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| **Signatures:**  |
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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*PI Signature* *(optional)*  *Date* |