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| **PI** |  | **JT#** |  |
| **Sponsor** |  |
| **Protocol Title** |  |

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| **Pre-MDG**  | **Complete** | **N/A** | Date Completed |
| Confirm Pre-Site Visit with Sponsor and PI  |[ ] [ ]   |
| Confirm receipt of Final protocol  |[ ] [ ]   |
| Confirm site selection by the sponsor  |[ ] [ ]   |
| Pharmacy feasibility Review (Phase I)  |[ ] [ ]   |
| Schedule review for MDG meeting / send out agenda 48 hours in advance |[ ] [ ]   |
| Add trial to PDL / personal tracker |[ ] [ ]   |
| Enterprise Wide: confirm sponsor approval for multi-site  |[ ] [ ]   |
| Verify with sponsor drug shipment plan/multisite capability(monitoring plan, supply shipments & 1572) |[ ] [ ]   |
| Verify if a NCTN Trial with IP shipped from PMB that an investigator at the site has the site as their shipping address*(If needed work with Pam Touchstone to update the shipping address of the investigator on their CTEP account).* |[ ] [ ]   |
| Multidisciplinary Group (MDG) | Complete | N/A | Date Completed |
| Confirm MDG approval from all voting members |[ ] [ ]   |
| Create protocol record in Jefftrial –(see req. field checklist)\*\* Add Key Personnel for each site to JeffTrial Staff List |[ ] [ ]   |
| Confirm MDG approval notification was created and sent:* PI, MDG Leader, CRO Directors, Regulatory Managers Budgets/Contracts, Site lead
 |[ ] [ ]   |
| Submit Protocol and MDG Approval to JCRI for Calendar Build |[ ]  [ ]  |  |
| Confirm Program assignment |[ ] [ ]   |
| Finalize MDG meeting minutes |[ ] [ ]   |
| Complete MDG Priority Form |[ ] [ ]   |
| Update Disease Map |[ ] [ ]   |
| Enterprise Wide: Confirm what ACH’s will participateConfirm Enrollment goal/site and Confirm PI Lead/site  |[ ] [ ]   |
| Protocol Facilitation Committee (PFC) | Complete | N/A | Date Completed |
| Complete PFC submission Form  |[ ] [ ]   |
| Prepare and send PFC submission packet: PFC submission form, Pharmacy, Imaging & Laboratory Manual, Protocol  |[ ] [ ]   |
| Identify Primary Coordinator |[ ] [ ]   |
| Identify Data Manager |[ ] [ ]   |
| Present protocol at assigned meeting |[ ] [ ]   |
| Confirm PFC approval |[ ] [ ]   |
| Complete Radiology Feasibility  |[ ] [ ]   |
| Complete IBC Initial submission  |[ ] [ ]   |
| E-W -Verify with sponsor data monitoring expectations/plan per site |[ ]  [ ]  |  |
| Protocol Review Committee (PRC) | Complete | N/A | Date Completed |
| Confirm receipt of Radiology Manual |[ ] [ ]   |
| Confirm approval Radiology Feasibility (needed for IRB submission) |[ ] [ ]   |
| Confirm IBC approval (needed for IRB submission) |[ ] [ ]   |
| Confirm Regulatory Coordinator |[ ] [ ]   |
| Confirm submission packet to regulatory: \*\*Disease Map, PRC questions, Priority Form, Radiology Feasibility, IBC submission |[ ] [ ]   |
| For NCTN studies, begin IROC credentialing  |[ ] [ ]   |
| For Surgical trials, begin surgical credentialing  |[ ] [ ]   |
| Confirm list of study staff with regulatory in Jefftrial. For NCTN studies, DTL  |[ ] [ ]   |
| IRB (when handled by CRO PSU) | Complete | N/A | Date Completed |
| Review ICF (check for any inconsistencies and for financial above) |[ ] [ ]   |
| Identify the IRB of Record for the trial (Jefferson or Central) |[ ] [ ]   |
| * If Central, find out from sponsor if we as site need to submit SAE and/or deviations or will sponsor submit on our behalf
 |[ ] [ ]   |
| * If we need to submit, identify staff and have them get access to central IRB system
 |[ ] [ ]   |
| * Identify reporting requirements of the sponsor/trial and the IRB
 |[ ] [ ]   |
| Confirm receipt of IRB approval / protocol training from regulatory |[ ] [ ]   |
| For NCTN studies, confirm PI sign off on DTL |[ ] [ ]   |
| Pharmacy/Drug | Complete | N/A | Date Completed |
| Confirm receipt of Pharmacy Manual |[ ] [ ]   |
| Create Beacon Build  |[ ] [ ]   |
| Confirm IDS & CRC has IVRS access, if needed |[ ] [ ]   |
| Confirm how to order study drug |[ ] [ ]   |
| Confirm receipt of study drug prior to activation if applicable |[ ] [ ]   |
| For NCTN studies, confirm PMB account & a shipping Investigator is available on site for each site participating |[ ] [ ]   |
| Confirm if IP is hazardous, if so, confirm use of Jefferson CSTD |[ ] [ ]   |
| Laboratory | **Complete** | **N/A** | Date Completed |
| Confirm receipt of lab manual |[ ] [ ]   |
| Confirm receipt of lab kits  |[ ] [ ]   |
| Confirm completion of TJU lab requisition sheets |[ ] [ ]   |
| Confirm SKCC-PK-PD can process research labs or if other lab is needed |[ ]  [ ]  |  |
| For NCTN studies, confirm access to Lab site |[ ]  [ ]  |  |
| Confirm Tissue request/shipping process/labels |[ ]  [ ]  |  |
| Data | **Complete** | **N/A** | Date Completed |
| If IIT – create database (RedCap) |[ ] [ ]   |
| If sponsored/NCTN-Confirm necessary staff have eCRF access |[ ] [ ]   |
| If sponsored/NCTN-Confirm necessary staff have completed eCRF training |[ ] [ ]   |
| Create Progress Notes |[ ] [ ]   |
| Create Source Documents |[ ] [ ]   |
| Imaging Portal Access |[ ]  [ ]  |  |
| QOL/Questionnaires Portal Access |[ ]  [ ]  |  |
| Miscellaneous | Complete | N/A | Date Completed |
| Arrival of sponsor equipment (EKG machine, BP cuff, etc.) |[ ] [ ]   |
| Confirm equipment functions properly |[ ] [ ]   |
| Equipment inspected by BioMed |[ ] [ ]   |
| Training of equipment operation is completed |[ ] [ ]   |
| Confirm biopsy setup |[ ] [ ]   |
| Financial/Contract | **Complete** | **N/A** | Date Completed |
| Confirm Calendar Build is complete in JeffTrial |[ ] [ ]   |
| Verify CTA is accurate |[ ] [ ]   |
| Confirm grant/account number was assigned  |[ ] [ ]   |
| Confirm contract is fully executed  |[ ] [ ]   |
| * Check if there is a set enrollment in the contract or competitive/open enrollment (if set number will need sponsor approval to enroll more)
 |[ ]  [ ]  |  |
| Review VPT/set up VPT review and training with JCRI |[ ] [ ]   |
| If NCTN trial, check Funding page/OPEN system |[ ]  [ ]  |  |
| Confirm ClinCard account is set up & ClinCard’s received |[ ]  [ ]  |  |
| Site Initiation Visit | **Complete** | **N/A** | Date Completed |
| Schedule SIV |[ ] [ ]   |
| Create SIV slides if necessary |[ ] [ ]   |
| Send SIV confirmation and agenda (Study team, Nursing, Regulatory, IDS) |[ ] [ ]   |
| Confirm SIV was completed |[ ] [ ]   |
| Create Training slides for Infusion/IRT & Schedule In-service |[ ]  [ ]  |  |
| Activation | **Complete** | **N/A** | Date Completed |
| Confirm ready to activate with sponsor (Greenlight) for each site |[ ] [ ]   |
| Confirm ready to activate internally (all boxes are checked) for each site |[ ] [ ]   |
| Send activation email (if E-W Note Clinician Lead per site) |[ ] [ ]   |
| Confirm Regulatory updated the JT record to “OPEN TO ACCRUAL” |[ ] [ ]   |
| Complete training for nurses at 925 Chestnut and other locations as needed |[ ] [ ]   |
| Discuss Clinical Pathways with RLO & Chris McNair |[ ] [ ]   |

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| Enterprise Wide Specifics | **Complete** | **N/A** | Date Completed |
| JeffTrial Personnel Update (per location) – by PSU Coordinator |[ ] [ ]   |
| JeffTrial Committees/Meetings Update (per site)- ongoing/site |[ ] [ ]   |
| Document all Site numbers for each site  |[ ] [ ]   |

**Completed By:**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Printed Name** | **Signature** | **Date** |