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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 participate  Confirm 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** |