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

|  |  |  |
| --- | --- | --- |
| General | Complete | N/A |
| Identify the regulatory coordinator  |[ ] [ ]
| Create contact list for binder  |[ ] [ ]
| Confirm receipt of MDG approval |[ ] [ ]
| Confirm receipt of PRC approval |[ ] [ ]
| Confirm receipt of IRB approval letter |[ ] [ ]
| Read protocol |[ ] [ ]
| Protocol Impact Statement completed and sent for review |[ ] [ ]
| Coordinate training for nurses at 925 Chestnut and other locations |[ ] [ ]
| Create personal notes – study highlights |[ ] [ ]
| Pharmacy/Drug |  |  |
| Send protocol to pharmacy to create chemo order template |[ ] [ ]
| Create chemo template/ nursing fact sheet (infusion drugs only)  |[ ] [ ]
| Drug has shipped and has been inventoried |[ ] [ ]
| Confirm receipt of pharmacy manual |[ ] [ ]
| Verify pharmacy template is accurate |[ ] [ ]
| Confirm how to get drug  |[ ] [ ]
| Confirm receipt of drug |[ ] [ ]
| Confirm IDS has IVRS access for drug reconciliation |[ ] [ ]
| Laboratory |  |  |
| Confirm receipt of lab manual |[ ] [ ]
| Confirm receipt of lab kits  |[ ] [ ]
| Complete yellow sheet |[ ] [ ]
| Data |  |  |
| Identify the data manager |[ ] [ ]
| Create progress notes |[ ] [ ]
| Confirm necessary staff have IVRS access |[ ] [ ]
| Create CRFs |[ ] [ ]
| Confirm necessary staff have completed eCRF training |[ ] [ ]
| Confirm necessary staff have eCRF access |[ ] [ ]

|  |  |  |
| --- | --- | --- |
| Miscellaneous | Complete | N/A |
| Arrival of sponsor equipment (EKG machine, BP cuff, etc.) |[ ] [ ]
| Confirm equipment functions properly |[ ] [ ]
| Training of equipment operation is completed |[ ] [ ]
| Confirm biopsy setup |[ ] [ ]
| Confirm receipt of radiology manual |[ ] [ ]
| Confirm receipt of radiology supplies |[ ] [ ]
| Confirm radiology setup |[ ] [ ]
| Financial/Contract |  |  |
| Obtain standard of care determination |[ ] [ ]
| Verify MCA is accurate |[ ] [ ]
| Confirm grant/account number was assigned  |[ ] [ ]
| Confirm contract is fully executed  |[ ] [ ]
| Review billing grid for accuracy |[ ] [ ]
| Study calendar is in JeffTrial |[ ] [ ]
| Site Initiation Visit |  |  |
| Schedule SIV |[ ] [ ]
| Create SIV slides |[ ] [ ]
| Confirm SIV occurred |[ ] [ ]
| Activation |  |  |
| Confirm ready to activate with sponsor |[ ] [ ]
| Confirm ready to activate internally (all boxes are checked) |[ ] [ ]
| Send activation email |[ ] [ ]

**Completed By:**

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