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

|  |  |  |
| --- | --- | --- |
| General | Complete | N/A |
| Current version of CRFs and lab manual sent to site |[ ] [ ]
| Site contact info sheet received  |[ ] [ ]
| Binder created for additional site |[ ] [ ]
| Protocol signature page is signed |[ ] [ ]
| Investigator brochure signature page is signed |[ ] [ ]
| CT.gov registration update is filed |[ ] [ ]
| Study Personnel Documentation |  |  |
| Delegation of authority log(s) are signed and filed |[ ] [ ]
| FDA 1572 is signed and filed |[ ] [ ]
| Financial disclosure certification forms for all investigators are signed and filed |[ ] [ ]
| SIV attendance sheet is filed |[ ] [ ]
| Protocol training emails are sent and filed |[ ] [ ]
| Protocol training logs are signed and filed |[ ] [ ]
| Current (within two years) signed and dated CVs are on file for all staff |[ ] [ ]
| Current medical licenses are on file for all relevant staff |[ ] [ ]
| Documents Sent to External Sponsor |  |  |
| FDA 1572 |[ ] [ ]
| IRB approval letter |[ ] [ ]
| Stamped consent form |[ ] [ ]
| Stamped patient materials |[ ] [ ]
| Other: |[ ] [ ]
| Financial/Contract |  |  |
| JCRI informed of addition of site |[ ] [ ]
| Contract with site executed |[ ] [ ]
| FDA |  |  |
| Amendment to add additional site submitted to FDA |[ ] [ ]

|  |  |  |
| --- | --- | --- |
| Laboratory Documents |  |  |
| CLIA |[ ] [ ]
| CAP |[ ] [ ]
| Lab permit |[ ] [ ]
| Lab normal/reference ranges |[ ] [ ]
| Lab director CV |[ ] [ ]
| IRB |  |  |
| Amendment submitted to TJU IRB to add additional site approved |[ ] [ ]
| Reviewed consent form prior to IRB submission |[ ] [ ]
| Site’s IRB initial approval received |[ ] [ ]
| Copy of IRB approved stamped ICF received |[ ] [ ]
| Copy of IRB approved patient materials received |[ ] [ ]
| Copy of initial IRB submission packet received |[ ] [ ]
| SIV |  |  |
| SIV slides created |[ ] [ ]
| SIV occurred |[ ] [ ]
| Activation |  |  |
| Activation letter sent to site |[ ] [ ]
| JeffTrial updated |[ ] [ ]

**Completed By:**

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