|  |  |  |  |
| --- | --- | --- | --- |
| **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 |  |  |

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| --- | --- | --- |
| 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** |