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

|  |  |  |
| --- | --- | --- |
| Before PRC Submission | Complete | N/A |
| MDG approval received |  |  |
| Confirm site selection |  |  |
| Complete MCSF |  |  |
| Send clinical project manger the completed research/standard of care table |  |  |
| Obtain draft contract and budget |  |  |
| Obtain consent form template |  |  |
| Obtain protocol |  |  |
| Confirm JeffTrial calendar was requested |  |  |
| Documents Sent to JCRI |  |  |
| Contract |  |  |
| Budget |  |  |
| Protocol |  |  |
| Informed consent form template |  |  |
| Investigator brochure/package insert |  |  |
| General |  |  |
| Identify the clinical research coordinator |  |  |
| Identify the data manager |  |  |
| Regulatory binder received or created |  |  |
| Protocol signature page is signed |  |  |
| Investigator brochure signature page is signed |  |  |
| CRFs received |  |  |
| Lab manual received |  |  |
| PRC approval received |  |  |
| IRB approval letter received |  |  |
| Stamped/approved study documents received |  |  |
| IRB approval and approved study documents were distributed to study team |  |  |
| IRB approval and approved study documents were uploaded to JeffTrial |  |  |
| FDA |  |  |
| IND or IDE application submitted to FDA |  |  |
| Safe to proceed letter received, or 30 days post FDA acknowledgment of receipt |  |  |
| IND or IDE number entered in JeffTrial |  |  |
| Study Personnel Documentation | Complete | N/A |
| JeffTrial staff list is current |  |  |
| 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 e-mails are sent 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 Sponsor |  |  |
| DOAL |  |  |
| FDA 1572 |  |  |
| Financial disclosure forms |  |  |
| CVs |  |  |
| Medical licenses |  |  |
| Investigator brochure signature page |  |  |
| Protocol signature page |  |  |
| IRB approval letter |  |  |
| Stamped consent form |  |  |
| Stamped patient materials |  |  |
| \*After Activation\* |  |  |
| CT.gov registration is filed |  |  |
| Obtain copy of executed contract |  |  |
| Protocol training logs are signed and filed |  |  |
| Send training logs to sponsor |  |  |

**Completed By:**

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