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