**Clinical Research Support Services (CRSS)**

**Guide for Clinical Trial Close-out**

**PI:**

**IRB#:**

**IO & GRANT#:**

**TITLE:**

**NON-SPONSORED IO for SURPLUS OR DEFICIT:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Action Items*****Check your contract for all line item costs*** – ***below are just a few*** | **Yes** | **No** | **Notes** |
| **Have you requested a detailed payment list from the CRO/Sponsor?** If not do not submit this form, until the list is received & reconciled |  |  |  |
| **Check for any open/outstanding invoices or encumbrances**. If any follow-up until they have cleared  |  |  |  |
| **PI and staff salary applied?**  If not, please apply |  |  |  |
| **Study Monitor Visits (In the Clinic: virtual or on-site)** Ask the study team for the name and date of visits. |  |  |  |
| **IRB & Other Costs** |  |  |  |
| **Check ALL your non-sponsored IO’s** for IRB fees i.e. Initial, Cont. Review, Changes in Research, etc. **When transferring to study, copy the text exactly as the IRB has entered** ***Note: Careful of dupes from prior non-sponsored IO transfers*.**  |  |  |  |
| **IRB Termination** acknowledgment of study closure.  |  |  |  |
| **Pharmacy Inventory Management** (Monthly or Quarterly) |  |  |  |
| **Pharmacy Monitor visits (Pharmacy virtual or on-site)** check with Pharmacy for the name/date of the visit. |  |  |  |
| **Change in Monitor (**if applicable) Name and date, check with the study team. |  |  |  |
| **Pharmacy Close-Out Fee** |  |  |  |
| **Record Retention/Archiving Fee** |  |  |  |
| **Unscheduled or Screen Fails -** Patient ID, and date, check with the study team |  |  |  |
| **Serious Adverse Events** (SAE), check with the study team |  |  |  |
| **IND Safety letters**, check with the study team |  |  |  |
| **Re-Consent,** Patient ID, and date needed, check with the study team |  |  |  |