**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 invoiceable line-item costs*** – ***below are just a few*** | **Yes** | **No** | **Notes** |
| **Have you requested a detailed payment list from the CRO/Sponsor?** Please remember to send a copy of the payment list along with the checklist when closing.  |  |  |  |
| Please ensure to review for any open or outstanding invoices or encumbrances. If there are any, please follow up until they have been cleared. |  |  |  |
| **PI and staff salary applied?**  If not, please apply |  |  |  |
| **IRB & Other Costs** |  |  |  |
| **Check all non-sponsored IOs for IRB fees (e.g., initial, continued review, changes in research, etc.). When transferring to study, copy the text exactly as entered by the IRB.*****Note: Careful of dupes from prior non-sponsored IO transfers*.**  |  |  |  |
| **IRB Termination** acknowledgment of study closure.  |  |  |  |
| **Pharmacy Inventory Management** (Monthly or Quarterly)  |  |  |  |
| **Study Monitor Visits (In the Clinic: virtual or on-site)** Ask the study team for the name and date of visits. |  |  |  |
| **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 for info. |  |  |  |
| **Serious Adverse Events** (SAE), check with the study team |  |  |  |
| **IND Safety letters**, check with the study team |  |  |  |
| **Re-Consent,** patient ID, and date. check with the study team for info.  |  |  |  |