|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Start-up Costs** |  |  |  |
| ❒ | Startup costs - Invoice due at contract execution; see contract for details |  |  |  |
|  |  |  |  |  |
|  | **IRB Costs** |  |  |  |
| ❒ | IRB Initial Fee |  |  |  |
| ❒ | IRB Continuation Fee |  |  |  |
| ❒ | IRB – Change in Research w/ consent (CIR) |  |  |  |
| ❒ | IRB – Change in Research w/o consent (CIR) |  |  |  |
| ❒ | IRB Close out |  |  |  |
|  | **Pharmacy Costs** |  |  |  |
| ❒ | Pharmacy Inventory Management; Quarterly |  |  |  |
| ❒ | Pharmacy Close Out Fee |  |  |  |
|  | Pharmacy Monitor visits |  |  |  |
|  | **Study Costs** |  |  |  |
| ❒ | Record Retention One-time fee at end of study |  |  |  |
| ❒ | Unscheduled, Screen Fail Visits |  |  |  |
| ❒ | Serious Adverse Events (SAE) Reporting |  |  |  |
| ❒ | Patient Reimbursement (stipends) |  |  |  |
| ❒ | Monitoring Visit per day |  |  |  |
| ❒ | Change in Monitor Fee |  |  |  |
| ❒ | IND Safety letters per letter / SAE Submissions per submission |  |  |  |
| ❒ | FDA Audit Fee |  |  |  |
| ❒ | Re-Consent Fee |  |  |  |
| ❒ | Administrative Protocol Am |  |  |  |
| ❒ | Annual Administrative Fee |  |  |  |
| ❒ | Screen Fails |  |  |  |
| ❒ | Study Close-out Fee |  |  |  |
|  |  |  |  |  |
|  | **Reminder - Things to do** |  |  |  |
| ❒ | CRF/Source data verification final |  |  |  |
| ❒ | For sponsor monitored studies: All data queries resolved and/or documentation exists for data discrepancies and unresolved data. |  |  |  |
| ❒ | Study drug/device accountability verified. |  |  |  |
| ❒ | Study drug/device returned to sponsor/CRO or destroyed. |  |  |  |
| ❒ | IRB notified that the study is complete/closed and a final report submitted to the IRB. |  |  |  |
| ❒ | Termination letter from IRB received. |  |  |  |
| ❒ | Final payment received and accounts payable reconciled. |  |  |  |
| ❒ | ORA Contacts for close out.  https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/clinical\_research.html |  |  |  |
| ❒ | Shared Services SP billing office notified to close out I/O number etc. Contact  https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/clinical\_research.html |  |  |  |
| ❒ | Send final enrollment log to sponsor to ensure all subjects are validated against Registry |  |  |  |
| ❒ | All earned revenue has been reconciled and received |  |  |  |
| ❒ | Revenue Transferred/SAP close out |  |  |  |
| ❒ | The PI has been notified of this final financial closeout etc. |  |  |  |