**Clinical Research Financial Management**

 **Close Out Process and Responsibilities**

**Department Responsibility**

Request a list of payments from Sponsor. Complete Clinical Research Account Close Out

Checklist. Ensure the account is reconciled according to the contract, sponsor and internal

budget and in compliance with university policy. All revenue must be received and expenses

posted to applicable GL accounts.

A completed checklist will be forwarded to Sponsored Projects Shared Services for

department-initiated close out requests.

**Sponsored Projects Shared Services Responsibility**

SPSS send the Clinical Research Account Closeout Checklist to departments for SPSS initiated

close out report.

SPSS will forward departmental close out requests to SOM Research Administration (applicable

contact) to initiate account close out.

 **Research Administration**

RA will review the account for close out. Advise departmental staff on any required adjustments

 and will copy SPSS to minimize duplicated requests. Review and approve close out requests

after any required adjustments have been completed. Send close out approval to SPSS.

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| --- | --- | --- | --- | --- |
|  | **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) |  |  |  |
| ❒ | Administrative Amendment Processing Fee |  |  |  |
| ❒ | IRB Close out |  |  |  |
|  | **Pharmacy Costs** |  |  |  |
| ❒ | Pharmacy Inventory Management; Quarterly |  |  |  |
| ❒ | Pharmacy Close Out Fee |  |  |  |
| ❒ | Pharmacy Monitor visits  |  |  |  |
|  |  |  |  |  |
|  | **Study Costs** |  |  |  |
| ❒ | Request list of received to date payments from Sponsor |  |  |  |
| ❒ | Effort applied to appropriate PI & Study team |  |  |  |
| ❒ | Record Retention One-time fee at end of study/Archiving Fee |  |  |  |
| ❒ | 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 |  |  |  |
| ❒ | 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. |  |  |  |
| ❒ |  |  |  |  |