#### The Queen’s Medical Center

#### Financial Binder Checklist

#### Federally-Sponsored Clinical Trials

Purpose: To ensure that all essential financial documents are reviewed, collected, filed and maintained appropriately at the site.

|  |  |  |
| --- | --- | --- |
| Study Title: |  | |
| RA# | | Cost Center |
| NCT | | IND/IDE |
| Principal Investigator: | | Email: |
| PI Address: | | Phone: |
| Study Coordinator (SC): | | Email: |
| SC Address: | | Phone: |
| Sponsor | | |
| Sponsor contact: | | Email: |
| Sponsor Address: | | Phone: |
| Grants Administrator: | | |

| Are all versions of the following documents present: | | | Draft | Complete | Amend | N/A | Location |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Contents List | Notes |  |  |  |  |  |
|  | Notice of Award | | | | |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  | Cost Reimbursement Research Subaward Agreement (from PTE to QMC) | | | | |  |  |
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|  |  |  |  |  |  |  |  |
|  | Indemnification/Insurance Certificate (if applicable) | | | | |  |  |
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|  | Certificate of Confidentiality (if applicable) | | | | |  |  |
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|  |  |  |  |  |  |  |  |
|  | Budget | | | | |  |  |
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|  |  |  |  |  |  |  |  |
|  | MCA (Coverage analysis) | | | | |  |  |
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|  | MCA signed by PI | | | | |  |  |
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|  | Consistency Checklist | | | | |  |  |
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|  |  |  |  |  |  |  |  |
|  | Physician Contracts Check | | | | |  |  |
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|  |  |  |  |  |  |  |  |
|  | Salary Confirmation by HR | | | | |  |  |
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|  |  |  |  |  |  |  |  |
|  | Study Personnel | | | | |  |  |
|  | SAM/OIG database check, Debarment form, Financial disclosure form, FCOI and human subjects training of **INVESTIGATOR** |  |  |  |  |  |  |
|  | SAM/OIG database check, Debarment form, Financial disclosure form, FCOI and human subjects training of **SUB-I** |  |  |  |  |  |  |
|  | SAM/OIG database check, Debarment form, Financial disclosure form, FCOI and human subjects training of **STUDY STAFF** |  |  |  |  |  |  |
|  | Device approvals from Medicare Contractor | | | | |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  | Financial Tracking Workbook Setup | | | | |  |  |
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|  | Subaward Agreement (QMC is PTE) | | | | |  |  |
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|  |  |  |  |  |  |  |  |
|  | External Vendor/Consultant Contract | | | | |  |  |
|  | Letter of Agreement/Contract |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  | Study Setup in Epic | | | | |  |  |
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|  | Study Setup in CTMS | | | | |  |  |
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|  | Guarantor Setup | | | | |  |  |
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|  | Cost Center Setup | | | | |  |  |
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|  |  |  |  |  |  |  |  |
|  | Payment to external vendors set up (DLS, HPL, Radiology Associates, etc) | | | | |  |  |
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|  |  |  |  |  |  |  |  |
|  | Subjects Information | | | | |  |  |
|  | Subject Screening/Enrollment Log |  |  |  |  |  |  |
|  | Monthly Subject Log |  |  |  |  |  |  |
|  | Research Subjects Registration Forms |  |  |  |  |  |  |
|  | W-9 Form (if applicable) |  |  |  |  |  |  |
|  | Close Out | | | | |  |  |
|  | Property Clearance form |  |  |  |  |  |  |
|  | Final Invention Statement and certification |  |  |  |  |  |  |
|  | Final Progress Report |  |  |  |  |  |  |
|  | Subrecipient Monitoring | | | | |  |  |
|  | Subrecipient Commitment form |  |  |  |  |  |  |
|  | Audit Report |  |  |  |  |  |  |
|  | Risk Assessment |  |  |  |  |  |  |
|  | Audit Certification Letter |  |  |  |  |  |  |
|  | Subrecipient Agreement |  |  |  |  |  |  |
|  | PTE Invoices |  |  |  |  |  |  |
|  | FFATA Reports |  |  |  |  |  |  |
|  | Time & Effort Reporting | | | | |  |  |
|  | Timesheets |  |  |  |  |  |  |
|  | Payroll Corrections |  |  |  |  |  |  |
|  | Accounting | | | | |  |  |
|  | Voucher – subject stipends |  |  |  |  |  |  |
|  | Vouchers – vendor payments |  |  |  |  |  |  |
|  | Purchase Orders |  |  |  |  |  |  |
|  | PTE Payments |  |  |  |  |  |  |
|  | Journal Entries |  |  |  |  |  |  |
|  | Manual Charge Logs |  |  |  |  |  |  |
|  | Salary Cap Adjustments |  |  |  |  |  |  |
|  | Travel Expenses |  |  |  |  |  |  |
|  | External Vendors/Consultants | | | | |  |  |
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ADDITIONAL NOTES

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