#### The Queen’s Medical Center

#### Financial Binder Checklist – Nonfederal studies

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: |  | |
|  | | | | |  | |

| Are all versions of the following documents present: | | | Draft | Complete | Amend | N/A |
| --- | --- | --- | --- | --- | --- | --- |
|  | Contents List | Notes |  |  |  |  |
|  | Confidentiality disclosure agreement | | | | |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  | Clinical trial agreement, inclusive of budget, and amendments | | | | |  |
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|  |  |  |  |  |  |  |
|  | Indemnification/Insurance Certificate | | | | |  |
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|  |  |  |  |  |  |  |
|  | Sponsor budget | | | | |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  | Detailed (QMC Internal) budget | | | | |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  | MCA (Coverage analysis) | | | | |  |
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|  |  |  |  |  |  |  |
|  | MCA signed by PI | | | | |  |
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|  | Consistency Checklist | | | | |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  | Other agreements (ie master clinical trial agreements, data use agreements) | | | | |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  | Financial Tracking Workbook Setup | | | | |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  | Device approvals from Medicare Contractor | | | | |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  | Pricing Agreement for QMC services (if necessary) | | | | |  |
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|  |  |  |  |  |  |  |
|  | Study Setup in Epic | | | | |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  | Study Setup in CTMS | | | | |  |
|  |  |  |  |  |  |  |
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|  | Guarantor Study Setup | | | | |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  | Study Setup with Finance (Cost Center Request) | | | | |  |
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|  |  |  |  |  |  |  |
|  | Accounts Payable Setup – Princing agreements and invoices from outside vendors | | | | |  |
|  | DLS |  |  |  |  |  |
|  | Radiology Associates |  |  |  |  |  |
|  | Hawaii Pathology Laboratories |  |  |  |  |  |
|  | Other outside vendors | UHCC, Hawaii Center of AIDS, Island Urology, etc |  |  |  |  |
|  | Non-QMC investigators | UCERA, OnCare and UH |  |  |  |  |
|  | Subject Stipend |  |  |  |  |  |
|  | Accounts Receivable Setup | | | | |  |
|  | Accrued Revenue Schedule |  |  |  |  |  |
|  | Sponsor/UHCC – Invoice patient visit(s) |  |  |  |  |  |
|  | Sponsor/UHCC – Receipt patient visit(s) |  |  |  |  |  |
|  | Sponsor/UHCC – Invoice for Pass-throughs |  |  |  |  |  |
|  | Sponsor/UHCC – Receipt for Pass-throughs |  |  |  |  |  |
|  | Submit/Email Journal Entry to Finance to record receivables | Sent to Cindy Cai xcai@queens.org |  |  |  |  |
|  | Other | | | | |  |
|  | Journal Entries |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  | W-9 forms (if applicable) |  |  |  |  |  |
|  | Close Out | | | | |  |
|  | Bill study close out fees (if applicable) |  |  |  |  |  |
|  | ??Offical study closure notification from sponsor/CRO |  |  |  |  |  |

ADDITIONAL NOTES

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