#### Queen Medical Center

#### Regulatory Binder Checklist

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

|  |  |
| --- | --- |
| Study Title:  |  |
| RA# | NCT | IND/IDE |
| Principal Investigator:  | Email: |
| PI Address: | Phone: |
| Sponsor |
| Sponsor contact:  | Email: |
| Sponsor Address: | Phone: |
|  |

| **Are all versions of the following documents present:** | **YES** | **NO** | **N/A** |
| --- | --- | --- | --- |
|  | **Contents List** | **Notes** |  |  |  |
| **1.** | **Contact Details** |
|  | 1.2 Site Visit Log |  |  |  |  |
|  | 1.2 Site Visit Correspondence and Corrective Action Plans |  |  |  |  |
|  | 1.3 Site Contact List |  |  |  |  |
| **2.** | **Study Communications** |
|  | 2.1 Correspondence |  |  |  |  |
|  | 2.2 Telephone Log  |  |  |  |  |
|  |  |  |  |  |  |
| **3.** | **Subject Information** |
|  | 3.1 Subject Screening/Enrollment Log – current, legible, dates and reason for screen failure  |  |  |  |  |
|  | 3.2 Subject Visit Tracking Log |  |  |  |  |
|  | 3.3 Blank Subject ID or Safety Card |  |  |  |  |
|  | 3.4 Immediately Reportable Adverse Event (IRAE) Log or equivalent |  |  |  |  |
|  | 3.5 Tissue Log |  |  |  |  |
| **4.** | **Protocol and Amendments (all versions)** |
|  | 4.1 Protocol |  |  |  |  |
|  | 4.2 Amendment(s) |  |  |  |  |
|  |  |  |  |  |  |
| **5.** | **Safety Information** |
|  | 5.1 Investigator Brochure/Approved Product Information |  |  |  |  |
|  | 5.2 Safety Reports |  |  |  |  |
|  | 5.3 External Adverse Events/Safety Reports |  |  |  |  |
|  | 5.4 Adverse Event Tracking Log |  |  |  |  |
| **6.** | **IEC/IRB/Regulatory** |
|  | 6.1 Submissions |  |  |  |  |
|  | 6.2 Opinions and Approvals (including Central IRB Justification form) |  |  |  |  |
|  | 6.3 Composition (for example, membership list) |  |  |  |  |
|  | 6.4 Correspondence |  |  |  |  |
|  | 6.5 Notification of safety reports |  |  |  |  |
|  | 6.6 Blank Set of Informed Consent Forms and Subject Information Sheets (all approved versions) |  |  |  |  |
|  | 6.7 Regulatory Authority Notification, Approval and Amendments |  |  |  |  |
|  | 6.8 Subject Advertisement and Appropriate Approvals |  |  |  |  |
|  | 6.9 Local or country specific required documentation |  |  |  |  |
|  | 6.10 Approved Questionnaires/Tools/Brochures/Other documents |  |  |  |  |
|  | 6.11 Deviations/Violations tracking |  |  |  |  |
| **7.** | **Contract/COI/MCA** |
|  | 7.1 Confidential Disclosure Agreement |  |  |  |  |
|  | 7.2 Clinical Trial Agreement/ Financial Contract |  |  |  |  |
|  | 7.3 Indemnification/Insurance Certificate (if applicable) |  |  |  |  |
|  | 7.4 Certificate of Confidentiality (if applicable) |  |  |  |  |
|  | 7.5 FDA 1572/Investigator Agreement/Qualified Investigator Undertaking Form |  |  |  |  |
|  |  |  |  |  |  |
|  | 7.6 Financial Disclosure Forms (if applicable) |  |  |  |  |
|  | 7.7 MCA – signed by PI |  |  |  |  |
|  | 7.8 Consistency Checklist |  |  |  |  |
| **8.** | **Study Personnel** |
|  | 8.1 Site Personnel Signature Form / DOA delegation of authority |  |  |  |  |
|  | 8.2 CV, Research HIPAA form, human subjects training of Investigator |  |  |  |  |
|  | 8.3 CV, Research HIPAA form, human subjects training of Sub-Investigator(s) |  |  |  |  |
|  | 8.4 CV, Research HIPAA form, human subjects training of other study staff  |  |  |  |  |
|  | 8.5 Other Relevant Documents | Licensure |  |  |  |
|  |  | IATA Training |  |  |  |
|  |  | Protocol Training |  |  |  |
|  |  | Ongoing Training logs |  |  |  |
|  | 8.6 Documentation of addition or removal of investigator or staff |  |  |  |  |
| **9.** | **Investigational Product/Test Article** |
|  | 9.1 IP Accountability Records (shipment, dispensing, return or destruction) |  |  |  |  |
|  | 9.2 Study Material Accountability Records |  |  |  |  |
|  | 9.3 Certificate of Analysis (including expiration dates) (if applicable) |  |  |  |  |
|  | 9.4 Randomization Codes/Unblinding Envelopes  |  |  |  |  |
|  | 9.5 Instructions for Handling IP and Trial-related Materials |  |  |  |  |
|  | 9.6 IP Storage Records (for example, refrigerator temperature log ) |  |  |  |  |
|  | 9.7 Pharmacy Manual |  |  |  |  |
|  | 9.8 IND/IDE application and amendments (if applicable) |  |  |  |  |
|  | 9.9 FDA 1571 (if applicable) |  |  |  |  |
| **10.** | **Case Report Form** |
|  | 10.1 Blank set of Case Report Forms  |  |  |  |  |
|  | 10.2 Site Copy of Completed data clarification forms |  |  |  |  |
|  | 10.3 Site Copy of Completed and signed CRFs |  |  |  |  |
|  |  |  |  |  |  |
| **11.** | **Laboratory (for all applicable laboratories)** |
|  | 11.1 Laboratory Certificates /Accreditation (including expiration dates) |  |  |  |  |
|  | 11.2 Reference Ranges (for medical/laboratory/technical procedures or tests included in the protocol) |  |  |  |  |
|  | 11.3 CV of Laboratory Head (if applicable) |  |  |  |  |
|  | 11.4 Record of Retained Body Fluids/Tissue Samples (if applicable) |  |  |  |  |
|  | 11.5 Laboratory Sample Storage Records (for example, temperature log) |  |  |  |  |
|  | 11.6 Lab kits available |  |  |  |  |
| **12.** | **Other Study Specific Documents** |
|  | 12.1 Confirmation List/Certificate(s) of Investigator Meeting Attendance |  |  |  |  |
|  | 12.2 Pre-Trial/Initiation Documentation |  |  |  |  |
|  | 12.3 Study Instruction Materials/User Manuals |  |  |  |  |
|  | 12.4 Authorization to Enroll |  |  |  |  |
|  | 12.5 Delegation of Responsibility  |  |  |  |  |
| **13.** | **Study Results/Reports/DSMB** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| **14.** | **Monitoring** |
|  | Clinical Research Associate (CRA) Visit Log, if study is monitored by Sponsor or CRO |  |  |  |  |
|  | CRA monitoring visit correspondence |  |  |  |  |
|  | Site response correspondence |  |  |  |  |
|  | If sponsor-investigator study, study monitoring procedures described? Copy of SOP |  |  |  |  |
| **15.** | **Confidential Site Documents**  |
|  | 15.1 Subject Identification List |  |  |  |  |
|  | 15.2 Signed Copies of Informed Consents and Subject Information Sheets (all approved versions) |  |  |  |  |
|  | 15.3 Source Documents Available for All Subjects |  |  |  |  |
|  | 15.4 Documentation of all payments |  |  |  |  |
| **16.** | **Study-specific documents: (to be specified )** |
|  | 16.1 Close out Letter |  |  |  |  |
|  | 16.2 IRB closure letter |  |  |  |  |
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ADDITIONAL NOTES

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