|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Laboratory File Checklist** | | | | | | |
| Administrative | | | | | | |
| Contact List and Organisation chart |  |  | |  | | |
| Version Control Log |  |  | |  | | |
| Certificate of accreditation or established QC/QA validation |  |  | |  | | |
| Central Laboratories Normal Reference Ranges (if applicable) and study analysis specific SOPs |  |  | |  | | |
| Study Protocol | | | | | | |
| **2.1 Current Approved Version (Signed)** |  |  | | |  | |
| **2.2 Superseded Approved Protocol(s)** |  |  | | |  | |
| Approvals | | | | | | |
| Ethics Approval |  |  | | |  | |
| Competent Authority approval |  |  | | |  | |
| Other |  |  | | |  | |
| Amendments ( REC & CA) |  |  | | |  | |
| Finance and contracts | | | | | | |
| Finance | | | | | | |
| Copy of financial information relating to the study (funding application/award letter/progress reports/Invoicing details) |  |  | | |  | |
| Contract(s) | | | | | | |
| Contracts/Service Level Agreements (+ amendments) between Sponsor(s) and Central Labs, Technical agreements |  |  | | |  | |
| Confidentiality Agreement(s) |  |  | | |  | |
| Research Team – Staff and Training | | | | | | |
| Delegation Duties Log for Laboratory Team |  |  | | |  | |
| Signed & Dated CVs & GCP Certificates for Research Team |  |  | | |  | |
| Staff Training Presentations/ Records |  |  | | |  | |
| SOP Section | | | | | | |
| SOP Index |  |  | | |  | |
| Insert name of SOP |  |  | | |  | |
| Insert name of SOP |  |  | | |  | |
| Insert name of SOP |  |  | | |  | |
| Insert name of SOP |  |  | | |  | |
| Incident and Non Compliance | | | | | | |
| Non Compliance Log |  |  | | |  | |
| Amendment and deviation log |  |  | | |  | |
| Associated correspondence |  |  | | |  | |
| Sample tracking | | | | | | |
| **8.1 Sample log** |  |  | | |  | |
| **8.2 Shipping documents** |  |  | | |  | |
| **8.3 Other study specific data collection forms and procedures** |  |  | | |  | |
| Monitoring and Audits |  |  | | |  | |
| Risk Assessment |  |  | | |  | |
| Monitoring | | | | | | |
| Monitoring Plan |  |  | | |  | |
| SIVdocumentationincluding presentation, letter, report, attendance log and updates |  |  | | |  | |
| Monitoringdocumentationincluding letter, report, attendance log and updates |  |  | | |  | |
| Close out visit documentation including letter, report, attendance log and updates |  |  | | |  | |
| Audit /Inspection Certificates |  |  | | |  | |
| Equipment and consumables | | | | | | |
| 10.1 Equpment maintenance log |  | |  | | |  |
| 10.2 Reagent preparation log |  | |  | | |  |