|  |
| --- |
| **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| **2.2 Superseded Approved Protocol(s)** |  |  |  |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  |
| Deviation Log |  |  |  |
| Amendment 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 EquIpment maintenance AND VALIDATION log |  |  |  |
| 10.2 Reagent preparation log |  |  |  |
| 10.2 SPECIMEN TRANSFER LOG |  |  |  |
| 10.2 SPECIMEN DESTRUCTION LOG |  |  |  |