|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **FDA INSPECTION CHECKLIST**  *Before a scheduled visit, the Research Team should complete the following activities:* | | | | |
| **Task** | **Items** | **Complete** | **N/A** | **Notes** |
| **Audit Notification** | | | | |
| **Notify all parties of impending audit** | Principal Investigator (PI) |  |  |  |
| Department Head |  |  |  |
| Entire Study Team |  |  |  |
| LSUHSC IRB |  |  |  |
| IRB Of Record, if not LSUHSC |  |  |  |
| Study Sponsor |  |  |  |
| Investigational Pharmacy |  |  |  |
| Administrative Official at Research Sites |  |  |  |
| **Reserve space for inspector(s)** | Workspace |  |  |  |
| Phone |  |  |  |
| Copier |  |  |  |
| Table |  |  |  |
| **Organization** | | | | |
| **Study Overview** | Prepare general overview of study |  |  |  |
| List of personnel and delegated responsibilities |  |  |  |
| **Subject List** | List of all subjects including name, contact info, enrollment & completion dates, and MRN |  |  |  |
| List of all subjects screened with enrollment or reason for not enrolled |  |  |  |
| **PI Current Studies** | List of PI’s current active studies |  |  |  |
| **File Management** | | | | |
| **Organize Files** | Protocol (all versions) |  |  |  |
| Investigator’s Brochure (all versions) |  |  |  |
| Protocol amendments |  |  |  |
| Form FDA 1572 or Declaration of Investigator (all versions) |  |  |  |
| CVs for PI, Sub-Investigators listed on 1572 or DOI |  |  |  |
| Copies of up-to-date training certificates for all research personnel |  |  |  |
| **IRB Files** | Initial Approval Letter and original informed consent |  |  |  |
| Amendment approvals with approved informed consent |  |  |  |
| Renewal approvals |  |  |  |
| Event Tracking Log |  |  |  |
| Resolution of Reportable Events |  |  |  |
| **Communication** | Sponsor Correspondence |  |  |  |
| CRO Correspondence |  |  |  |
| Monitoring Log |  |  |  |
| **Laboratory** | Laboratory Certification(s) |  |  |  |
| Laboratory Normal Ranges |  |  |  |
| CV of Lab Director |  |  |  |
| **Drug Accountability** | Receipt of Drug |  |  |  |
| Dispensing Log |  |  |  |
| Return Log |  |  |  |
| **Adverse Events** | SAE Reports made to Sponsor |  |  |  |
| SAE Reports received from Sponsor |  |  |  |
| **Subject Documents** | Completed CRFs for each subject |  |  |  |
| Source documents/medical records for each subject |  |  |  |
| **Device Accountability** | Receipt of Device |  |  |  |
| Dispensing Log, where applicable |  |  |  |
| Return Log, where applicable |  |  |  |
| **Data Review**  *Complete and note any issues to discuss with the PI or others* | | | | |
| **Each Subject’s Study Documents** | Inclusion/Exclusion Criteria |  |  |  |
| Reason for exclusion documented |  |  |  |
| CRFs completed for each enrolled subject |  |  |  |
| Source documentation for all CRF entries |  |  |  |
| Data clarification issues satisfied |  |  |  |
| Consent obtained from all subjects screened/enrolled |  |  |  |
| Correct version of informed consent signed |  |  |  |
| Notes to File present as appropriate |  |  |  |
| **Source Documentation/ Medical Records Documenting Data** | Condition of subject at time of entry into the study |  |  |  |
| All exposures to test articles |  |  |  |
| Concomitant medications |  |  |  |
| Clinical assessments of subjects during study |  |  |  |
| Laboratory reports |  |  |  |
| Diagnostic test reports |  |  |  |
| Diagnostic test films |  |  |  |
| Dose modifications |  |  |  |
| Adverse Events |  |  |  |
| Protocol Exceptions |  |  |  |
| Early Withdrawl |  |  |  |

*This document has been created by the LSUHSC-NO IRB and CTO as guidance to help investigators and research staff throughout the process of a Food and Drug Administration (FDA) inspection.*