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| **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.*