|  |  |
| --- | --- |
| **Information to Collect Upon Notification of an FDA Inspection** | |
| Name of individual taking the call and the call date: |  |
| FDA Investigator Contact Information: | Name:  Title:  Telephone #: |
| Additional FDA Investigators’ Names |  |
| Start Date of the Inspection: |  |
| Expected Duration of the Inspection: |  |
| Who/ what is being inspected?  *(Clinical Trial, PI, Other)* |  |
| What is the reason for the inspection? | ☐ Routine, i.e. IND  ☐ Directed or For Cause  ☐ Follow-up, i.e. to 483  ☐ Other: |
| Does the FDA want specific personnel available? |  |
| Does the FDA want specific documents available? |  |

**Preparatory Activities for FDA Inspection**

|  |  |  |  |
| --- | --- | --- | --- |
| **Notify all applicable parties:** | **Completed**  **Yes N/A** | | **Comments** |
| Sponsor | ☐ | ☐ |  |
| IRB | ☐ | ☐ |  |
| Study Staff | ☐ | ☐ |  |
| Pharmacy | ☐ | ☐ |  |
| Department Chair | ☐ | ☐ |  |
| Other: | ☐ | ☐ |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Designate an FDA inspection team and assign responsibilities:** | **Completed**  **Yes** **No** | | **Comments** |
| Room reservation for FDA inspection | ☐ | ☐ |  |
| Review of staff and clinic schedules | ☐ | ☐ |  |
| Document Preparation:   * Regulatory file * Subject records * Pharmacy records | ☐  ☐  ☐ | ☐  ☐  ☐ |  |

|  |  |  |
| --- | --- | --- |
| **Compile the following:** | **Completed**  **Yes**  **No** | **Comments** |

|  |  |  |  |
| --- | --- | --- | --- |
| A List of the PI’s currently active protocols | ☐ | ☐ |  |
| A general overview of the study to be reviewed for internal use, *e.g. a protocol abstract, the # of subjects screened for enrollment, the # of subjects who received the test article, any associated reportable events, summary of previously known areas of non-compliance and corrective action*  *plans implemented, etc.* | ☐ | ☐ |  |

**If time permits and advanced notice of the FDA Inspection is received**

| **Organize all Regulatory Files by General Heading and in Chronological Order:** | **Completed**  **Yes**  **No** | **Comments** |
| --- | --- | --- |

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol (all versions, amendments and renewals) | ☐ | ☐ |  |
| Informed Consent Documents (all versions including screening consent forms) | ☐ | ☐ |  |
| IRB Approval Letters | ☐ | ☐ |  |
| Reportable Events | ☐ | ☐ |  |
| Protocol Deviations | ☐ | ☐ |  |
| DSMB summary reports and documentation of submission to the IRB | ☐ | ☐ |  |
| IND Safety Reports | ☐ | ☐ |  |
| Investigator’s Brochure/ Device Manual (All Versions) | ☐ | ☐ |  |
| Sponsor Correspondence | ☐ | ☐ |  |
| Any other correspondence pertinent to the study | ☐ | ☐ |  |
| Clinicaltrials.gov - documentation of protocol registration submission, approval, activation and de- registration | ☐ | ☐ |  |

| **Organize all Regulatory Files by General Heading and in Chronological Order:** | **Completed**  **Yes**  **No** | **Comments** |
| --- | --- | --- |

|  |  |  |  |
| --- | --- | --- | --- |
| Delegation/signature log | ☐ | ☐ |  |
| Form 1572 (all versions) | ☐ | ☐ |  |
| Financial Disclosure Forms for all involved in the treatment and evaluation of subjects | ☐ | ☐ |  |
| 1571 | ☐ | ☐ |  |
| CVs | ☐ | ☐ |  |
| Licenses | ☐ | ☐ |  |
| Training records:   * GCP * Protocol Specific | ☐  ☐ | ☐  ☐ |  |
| Monitoring Visit Log | ☐ | ☐ |  |
| Subject Screening Log | ☐ | ☐ |  |
| Subject Enrollment Log | ☐ | ☐ |  |
| Randomization Log (if applicable) | ☐ | ☐ |  |

| **Organize Research Subject Records and Ensure Availability of the Following:** | **Completed**  **Yes** **No** | **Comments** |
| --- | --- | --- |

|  |  |  |  |
| --- | --- | --- | --- |
| Original signed and dated Informed Consent Documents for each research participant along with addendums as applicable | ☐ | ☐ |  |
| Completed Case Report Forms | ☐ | ☐ |  |
| Source documentation to support the subject:   * + Met all eligibility criteria   + Received test article per protocol   + Had f/u visits performed per protocol windows   + Had laboratory tests per protocol and lab reports were acknowledged by the PI or designee   + Had other diagnostic tests as applicable per protocol   + Was evaluated for and treated as applicable for AEs | ☐  ☐  ☐  ☐  ☐  ☐ | ☐  ☐  ☐  ☐  ☐  ☐ |  |
| Documentation for protocol exceptions or deviations | ☐ | ☐ |  |
| Ensure resolution of all queries | ☐ | ☐ |  |
| Documentation of early terminations | ☐ | ☐ |  |

| **Organize and Ensure Completion of Pharmacy Binder:** | **Completed**  **Yes**  **No** | **Comments** |
| --- | --- | --- |

|  |  |  |  |
| --- | --- | --- | --- |
| CV of pharmacist (s) | ☐ | ☐ |  |
| CV of key pharmacy personnel | ☐ | ☐ |  |
| Licenses of pharmacy personnel | ☐ | ☐ |  |
| Most recent version of the protocol | ☐ | ☐ |  |
| Most recent version of IB or package insert | ☐ | ☐ |  |
| Drug supply agreement | ☐ | ☐ |  |
| Participant prescriptions | ☐ | ☐ |  |
| Accountability logs | ☐ | ☐ |  |
| Ordering/ shipping receipts | ☐ | ☐ |  |
| Documentation of study drug transfers, returns or destruction | ☐ | ☐ |  |

| **Organize and Ensure Completion of Study Specific Logs:** | **Completed**  **Yes** **No** | **Comments** |
| --- | --- | --- |

|  |  |  |  |
| --- | --- | --- | --- |
| Specimen logs (if applicable) | ☐ | ☐ |  |
| Temperature Logs for refrigerators / freezers  (if applicable) | ☐ | ☐ |  |
| Equipment logs (if applicable)   * + Calibration   + Inspection   + Training | ☐  ☐  ☐ | ☐  ☐  ☐ |  |

**References**

FDA Inspection Classification Database

FDA Guidance for Inspections

The Center for Drug Evaluation and Research, Clinical Investigator Inspection Search Database

FDA Warning Letters

Office of Sponsored Programs and Research Support (OSPARS)

HRP Policies and Procedures Chapter 16: Procedures for FDA Inspections of Investigator Sites