## COE-102.00

## Attachment 1 – Audit Checklist

**PREPARING FOR AN AUDIT CHECKLIST**

|  |  |  |  |
| --- | --- | --- | --- |
| **1. ORGANIZATION** | **YES** | **N/A** | **COMMENTS** |
| ***Notify all parties***  | Sponsor(s) (if an FDA audit) |  |  |  |
|  | WVU IRBIRB of Record (if not local oversight) |  |  |  |
|  | Principal Investigator/Sub - Investigators |  |  |  |
|  | Investigational Pharmacy |  |  |  |
|  | Laboratories |  |  |  |
|  | Medical records |  |  |  |
|  | Administration: -Office of Sponsored Programs (OSP)-Internal Audit Office |  |  |  |
|  | Legal counsel |  |  |  |
|  | Clinical Trials Center of Excellence |  |  |  |
|  | Reserve work space for the auditor |  |  |  |
| ***General overview of the study*** | Prepare a general overview of the study |  |  |  |
|  | Ensure applicable SOPs are readily available |  |  |  |
| List all personnel and responsibilities delegated and provide evidence of study related training for all study personnel.  |  |  |  |
| ***List of subjects*** | To be kept as a reference for site research staff to facilitate retrieval of information during the audit: List all subjects screened, consented, including name, address, and/or phone number, date enrolled and/or randomized and completed, medical record number  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **2. FILES MANAGEMENT** | **YES** | **N/A** | **COMMENTS** |
| ***Organize all regulatory files by general heading arranged in chronological order*** | Signed, dated and approved Protocol (all versions) and amendments |  |  |  |
|  | Investigator's Brochure (all versions) |  |  |  |
|  | Form FDA 1572 or Investigator Agreement (all versions) |  |  |  |
|  | CVs for PI and Sub - Investigators listed on all versions of Form FDA 1572/Investigator Agreement |  |  |  |
| ***IRB files*** | Approval letter (initial) for initial protocol with original Informed Consent Form |  |  |  |
|  | Amendment approval(s) with approved informed consent (if applicable) |  |  |  |
|  | Informed consent forms (originals) for enrolled subjects |  |  |  |
|  | Informed consents for screened subjects |  |  |  |
|  | Status reports for: |  |  |  |
|  | 1. Yearly renewal(s)
 |  |  |  |
|  | 1. Serious Adverse Events (SAE) and Adverse Events (AE)
 |  |  |  |
|  | 1. Deaths
 |  |  |  |
|  | 1. Study Hold or Termination
 |  |  |  |
|  | 1. Final summary
 |  |  |  |
| ***Communications*** | Sponsor correspondence |  |  |  |
|  | CRO correspondence |  |  |  |
|  | IRB Correspondence |  |  |  |
|  | Monitoring log |  |  |  |
| ***Laboratory*** | Laboratory certification and normal ranges |  |  |  |
|  | Logs to include: |  |  |  |
| ***IP*** | 1. Receipt
 |  |  |  |
| ***accountability*** | 1. Dispensing
 |  |  |  |
|  | 1. Return
 |  |  |  |
| ***Subject documents*** | Completed CRFs for each subject enrolled |  |  |  |
| Source documents for each subject enrolled |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **3. REVIEW** | **YES** | **N/A** | **COMMENTS** |
| ***Collect and review for each subject enrolled*** | CRFs completed for each subject enrolled |  |  |  |
|  | Data correction forms for CRFs |  |  |  |
| ***Medical records and/or study files*** | Source documents for each subject enrolled that document the following: |  |  |  |
| 1. Medical History of subjects at time of entry into the study (i.e., all inclusion/exclusion criteria are met)
 |  |  |  |
|  | 1. Eligibility Determination and sign off
 |  |  |  |
|  | 1. Concomitant medications
 |  |  |  |
|  | 1. Clinical assessments of the subject during the course of the study
 |  |  |  |
|  | 1. Laboratory reports
 |  |  |  |
|  | 1. Diagnostic tests
 |  |  |  |
|  | 1. Dose modifications
 |  |  |  |
|  | 1. SAEs or AEs/death
 |  |  |  |
|  | 1. Protocol and Subject Deviations
 |  |  |  |
|  | 1. Early termination
 |  |  |  |
|  | 1. Patients lost to Follow ups/ Patients still in study
 |  |  |  |