|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Reviewer Name:** | |  | **Date of Review:** | |  | | | | | |
| **Protocol Number:** | |  | **Reviewed From Date:** | |  | | | | **Reviewed Through Date:** |  |
| **Instructions:** This Regulatory File Review Tool, along with the ICH Regulatory File Guidelines (site ICH section 8), is recommended for reviewing regulatory files for protocols. Review of the regulatory file should be completed at a minimum *once* during the active study period *or annually* if the study is long term. For each criteria reviewed in Section I, check the appropriate boxes. Any issues (‘No’ indications or comments) noted within Section I are summarized in Section II including the resolution to the issue(s) / corrective action, date resolved, and the name of the individual responsible for corrections. When the review and any corrective actions are completed, this Regulatory File Review Tool will be signed and dated by the QA Reviewer and filed within the Quality Management binder. Note: Other protocol-specific indicators or criteria may be added as determined by site staff. | | | | | | | | | | |
| **SECTION I – DOCUMENTS AND CRITERIA** | | | | | | | | | | |
| **Document** | **Criteria** | | | **YES**  **√** | | **NO**  **√** | **N/A**  **√** | **Comments** | | |
| **Study Identification** | Is the identification of the site, including name of PI, study location(s), Protocol Number and title, etc. present and correct? | | |  | |  |  |  | | |
| **IRB/IEC Approvals** | Is the Initial IRB Approval for the Protocol and the Informed Consent present? | | |  | |  |  |  | | |
| Are subsequent approvals present (i.e., Continuing / Annual Review, amendments) | | |  | |  |  |  | | |
| Are all applicable Advertisements, Recruitment Scripts, Participant Information Materials approved by IRB and on file? | | |  | |  |  |  | | |
| Are periodic Reports present? | | |  | |  |  |  | | |
| **IRB/IEC Membership** | Is the IRB Roster or Membership composition on file? Has it been updated annually? | | |  | |  |  |  | | |
| If the IRB does not provide a roster, is there a letter on file stating the names are not released? | | |  | |  |  |  | | |
| **Non UCLA Regulatory Approvals** | If there is a non-UCLA site, is there documentation of regulatory body approval or clearance on file? | | |  | |  |  |  | | |
| **Local Regulatory Approvals** | Are all local, state, and/or special authorizations related to the protocol maintained and up-to-date? | | |  | |  |  |  | | |
| **Federal Wide Assurances (FWA)** | Is there a current Federal Wide Assurance document from OHRP present? Is the expiration date present? | | |  | |  |  |  | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **SECTION I – DOCUMENTS AND CRITERIA (cont.)** | | | | | | |
| **Document** | **Criteria** | | **Yes**  **√** | **No**  **√** | **N/A**  **√** | **Comments** |
| **Protocol** | Is a current and valid copy of the Protocol on file? | |  |  |  |  |
| Are all previous versions of the Protocol on file? | |  |  |  |  |
| Have any lapses been documented properly? | |  |  |  |  |
| **Informed Consent Form(s)** | Is a current and valid copy of the Informed Consent Form on file? | |  |  |  |  |
| Are all previous versions of the Informed Consent Form on file? | |  |  |  |  |
| Have any lapses been documented properly? | |  |  |  |  |
| **1572/IOR Agreement** | Is there a 1572 (for IND studies), or an Investigator of Record Agreement on file? | |  |  |  |  |
| Is the agreement current and accurate? Has the agreement been signed by PI? | |  |  |  |  |
| **Serious Adverse Events (SAE)** | Are all SAEs that have been reported to FDA and IRB/IEC present in the file? | |  |  |  |  |
| **Safety Reports** | Are Safety Reports/Memos for this protocol on file? |  | |  |  |  |
| Have these safety reports been submitted to IRB/IEC? |  | |  |  |  |
| **Study-specific Procedures / Manual of Procedures** | Does the file contain the study-specific procedures or the Manual of Procedures (MOP)? | |  |  |  |  |
| **Sample Case Report Forms (CRF) / eCRF(s)** | Are final (actually used) versions of the sample CRF(s) or other forms used for entering data on file? | |  |  |  |  |
| Are final (actually used) versions of the Source Document Workbook (eCRF) that is provided by the sponsor on file? Note: Dated documentation of all changes to the database during the active period of the trial must be maintained. | |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SECTION I – DOCUMENTS AND CRITERIA (cont.)** | | | | | | | | | | |
| **Document** | **Criteria** | **Yes****√** | | **No****√** | | **N/A****√** | | **Comments** | | |
| **Curricula Vitae (CVs)** | Are CVs present for Principal Investigator and all sub-investigators listed on the 1572/IOR? Are they current? (< 5 years of current date)  Basic requirements of the CV include current work address, professional title, degrees, and current relevant licensure. | |  | |  | |  | |  | |
| **Medical Licenses** | Are Medical Licenses present for Principal Investigator and all sub-investigators listed on the 1572/IOR? Are they current? | |  | |  | |  | |  | |
| **Protocol Deviations** | Are all Protocol Deviations that have been submitted to the IRB/IEC present? | |  | |  | |  | |  | |
| **Financial Disclosure** | Are financial disclosure forms for all key personnel present? | |  | |  | |  | |  | |
| **Investigator Brochures / Package Inserts** | Are Investigator Brochures present, current, and available for investigational products? Have these been submitted to the IRB (if applicable)? | |  | |  | |  | |  | |
| Are package inserts present, current, and available for approved drugs? Have these been submitted to the IRB (if applicable)? | |  | |  | |  | |  | |
| **Laboratory Normals and Accreditations** | Are laboratory certifications and accreditations present for U.S. labs? (CAP and CLIA Accreditation, JCAHO, CLIA Compliance, CLIA exempt, etc.) | |  | |  | |  | |  | |
| If not a U.S. lab, are there other certificates of qualification for the lab on file? If not, is a statement included explaining the reason and a description of the standard being used? | |  | |  | |  | |  | |
| Are approvals from collaborating Research Laboratories on file? | |  | |  | |  | |  | |
| Are Normal Ranges for all protocol-required tests on file? This must include all clinical laboratory tests required by the protocol, the unit of measure, the laboratory name, and the date of the document. | |  | |  | |  | |  | |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SECTION I – DOCUMENTS AND CRITERIA (cont.)** | | | | | | | | | | |
| **Document** | **Criteria** | **Yes****√** | | **No****√** | | **N/A****√** | | **Comments** | | |
| **Test Article** | Is there a sample Test Article label on file? | |  | |  | |  | |  | |
| Are the Test Article Accountability Records accurate, current, and on file? Do they agree with the actual inventory on hand? | |  | |  | |  | |  | |
| Are instructions (protocol-specific MOP) for the storage, mixing, and handling of Test Article easily accessible and on file? | |  | |  | |  | |  | |
| Are Shipping Records for Test Article documenting the receipt date, quantity, lot numbers of all test articles (if open-label study) on file? | |  | |  | |  | |  | |
| Is the randomization list and decoding procedures for Blinded Test Article on file? | |  | |  | |  | |  | |
| Are Test Article Temperature Logs on file? | |  | |  | |  | |  | |
| **Specimen Retention** | Are Specimen Retention Records on file? | |  | |  | |  | |  | |
| **Site Monitoring Log and Reports** | Are copies of Site Monitoring Logs and Reports on file? (Initiation, Interim Monitoring, Close-out) | |  | |  | |  | |  | |
| **Study Personnel Signature/ Responsibility List** | Is the Study Personnel Signature/Responsibility List present for all individuals authorized to make entries in study records? | |  | |  | |  | |  | |
| **ID Code List** | Is the ID Code List present in the file? | |  | |  | |  | |  | |
| **Screening/ Enrollment Log** | Is the Screening/Enrollment Log present and up-to-date? | |  | |  | |  | |  | |
| **Sponsor Correspondence** | Does the file contain all up-to-date correspondence between the site and sponsor? | |  | |  | |  | |  | |
| **Internal Correspondence** | Does the file contain all up-to-date internal correspondence? | |  | |  | |  | |  | |
| **Telephone Contact Reports** | Does the file contain up-to-date Telephone Contact Reports? | |  | |  | |  | |  | |
| **Regulatory Review History** | Does the file contain an up-to-date Regulatory Review History Form? | |  | |  | |  | |  | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **SECTION I – DOCUMENTS AND CRITERIA (cont.)** | | | | | | |
| **Document** | **Criteria** | **Yes****√** | **No****√** | **N/A****√** | **Comments** | |
| **Final Reports** | If applicable, is the Final Report to the IRB/IEC present? |  |  |  |  | |
| If applicable, is the Final Report to the sponsor present? |  |  |  |  | |
| **Notes to File** | Does the file contain relevant study-specific notes to file? |  |  |  |  | |

|  |  |  |
| --- | --- | --- |
| **SECTION II – ISSUES AND RESOLUTIONS (CORRECTIVE ACTION TAKEN)** | | |
| **Issues and Corrective Actions Noted Recommend a separate column for corrective actions.** **(refer to “comments” in above Section I)** | **Date Resolved** | **Resolved by (Name)** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Quality Assurance Review Completion: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Person Performing QA Review**