**Site Investigator File (SIF) QA Review Checklist**

**PART 1: Trial Details** *[To be completed by the Central Trial Coordinating Team]*

|  |  |
| --- | --- |
| **Protocol Title:** | <Insert Protocol Title> |
| **Protocol Number:** | <Insert Protocol Number> | **Sponsor-Investigator:** | <Insert Name> |
| **Peer Reviewer Name:** | <Insert Name> | **Date QA Review:** | <Insert Date> |
|  |
| **Site Name:** | <Insert Site Name> | **Site Code:** | <Insert Site Code or “NA”> |
| **Reason for Review** | [ ]  Routine Annual[ ]  Ad hoc; *specify:* | **SIF Format/Source** | *<Delete those below which are Not Applicable>* [ ]  Paper SIF Binder: Specify name of Binder: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Florence eBinders; Specify name of Binder: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  SharePoint; Specify location & name of Folder: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Network Drive; Specify location & name of Folder: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Other; Specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Current Approved Protocol Version No. and Date:** | Version No: ­­­­­<Insert No.> Dated: <Insert Date> *<Add others as required>* | **Current Approved Site-Specific PICF/s Version No. and Date/s:** | <*Add others/Delete above as required>* Version No: ­­­­­<Insert No.> Dated: <Insert Date>Version No: ­­­­­<Insert No.> Dated: <Insert Date>  |
| **Indicate the SIF Folders Not Subject or Not Applicable for Review** | Folders and/or documents which are NOT subject to this SIF QA Review have been indicated in the Review Checklist below as “N/A”, by the Central Trial Coordinating Team during the TMF QA Planning stage. |

**PEER REVIEWER COMPLETION INSTRUCTIONS:**

In accordance with the timelines provided on the TMF QA Planning Form, the Peer Reviewer must review each section of the Site Investigator File (SIF) clearly documenting any findings on this checklist. Using this checklist, the Peer Reviewer must:

* Indicate whether a document is present/on file within its corresponding folder/section and note any discrepancies
* Check for overall TMF consistency, logic, completeness and accuracy
* Check the currency of all documentation filed i.e. is the document current/in date or expired
* Check for any duplications of documents/mis-filed documents
* Check for use of consistent versioning, tracking and naming conventions
* Indicate whether any follow-up/CAPAs are required

**PART 2: SIF QA Review Checklist**

*[Central Trial Coordinating Team to initially indicate in the Checklist below which Folders/Sections of the SIF are “NA” for QA review”]*

*[SIF QA Reviewer to complete remaining checklist during QA review]*

| **FOLDER/ SECTION** | **TITLE** | **DOCUMENTS** | **PRESENT IN FILE?** | **PEER REVIEWER COMMENTS** including anyFollow Up Required | **CORRECTIVE ACTION or RESPONSE**Completed by Research Team Member Responsible for TMF/SIF |
| --- | --- | --- | --- | --- | --- |
|  |  |  | **YES** | **NO** | **NA** |  |  |
| **1.0** | **PARTICIPATING SITE TEAM** |
| **1.1** | **Contact List**  | Participating Site Contact List |[ ] [ ] [ ]     |  |
| **1.2** | **Delegation and Signature Log** | Copy of the Signature and Delegation Log |[ ] [ ] [ ]   |  |
| **1.3** | **CVs** | Original CV of the Site Principal Investigator* Signed and dated within last two years
 |[ ] [ ] [ ]   |  |
|  |  | Original CV of Study Coordinator * Signed and dated within last two years
 |[ ] [ ] [ ]   |  |
|  |  | Copies of Medical / AHPRA Licenses * If applicable
 |[ ] [ ] [ ]   |  |
| **1.3.1** | **Other CVs** | Original Curriculum Vitae from all Site staff involved in the trial * Signed and dated within last 2 years
 |[ ] [ ] [ ]   |  |
|  |  | Copies of Medical / AHPRA Licenses * If applicable
 |[ ] [ ] [ ]   |  |
| **1.4** | **GCP Training Certificates** | GCP Training Certificate from the Site Principal Investigator |[ ] [ ] [ ]   |  |
|  |  | GCP Training Certificate from the Study Coordinator |[ ] [ ] [ ]   |  |
| **1.4.1** | **Other GCP Training Certificates** | GCP Training Certificate from all other key research team personnel from the Participating Site |[ ] [ ] [ ]   |  |
| **1.5** | **EDC Training Certificates** | * Copies of site staff EDC Training Certificates/ Certifications, if applicable
* Copies of site staff completed CRF Exercises/ Knowledge Assessments, if applicable
 |[ ] [ ] [ ]   |  |
| **1.6** | **Other Training Certificates** | Copies of other training certificates from all Site staff involved in the study* If applicable
 |[ ] [ ] [ ]   |  |
| **1.7** | **Wet Ink Signature Log** | Copy of the site-specific Wet-Ink Signature Log* If applicable
 |[ ] [ ] [ ]   |  |
| **2.0** | **PROJECT MANAGEMENT** |
| **2.1** | **Site Selection Documentation** | Copies of Site Selection documentation* If applicable
 |[ ] [ ] [ ]   |  |
| **2.2** | **Internal Team Communication** | Copies of meeting minutes, emails, etc and all other significant correspondence |[ ] [ ] [ ]   |  |
| **3.0** | **PROTOCOL/PROTOCOL AMENDMENTS** |
| **3.1** | **Protocol Version Tracker** | Site Specific Protocol Version Tracker * Paper Log or Florence eLog
 |[ ] [ ] [ ]   |  |
| **3.2** | **Signed Protocol Signature & Investigator Agreement Pages** | Copy of the Signed Protocol Signature Pages – signed by the Site Principal Investigator* Current & Superseded Protocols
 |[ ] [ ] [ ]   |  |
| **3.3** | **Local Site Non-Compliance Log** | Copy of the Site-Specific Non-Compliance Log* Paper Log or Florence eLog
 |[ ] [ ] [ ]   |  |
| **3.4** | **Local Site Non-Compliance Reports**- Deviations from GCP or the protocol | Copies of Non-Compliance Report Forms* Completed and submitted by the participating sites
 |[ ] [ ] [ ]   |  |
|  |  | Copies of Non-Compliance Review Forms* Completed and assessed by Sponsor-Investigator
 |[ ] [ ] [ ]   |  |
| **3.5** | **Serious Breaches and CAPA Documents**- From Sponsor-Investigator | Site-Specific Corrective and Preventive Action Plans * Completed and submitted by participating
 |[ ] [ ] [ ]   |  |
|  |  | Copy of any Site-Specific Corrective and Preventive Action Plan Reviews* Completed and assessed by the Sponsor-Investigator and/or Sponsor detailing any corrective and preventative action to be taken in addressing breaches
 |[ ] [ ] [ ]   |  |
|  |  | Site-Specific CAPA Tracking Log * Maintained by Trial Coordinator
 |[ ] [ ] [ ]   |  |
| **3.6** | **Copy of all Serious Breach reports to Sponsor and local RGO or Regulatory** **Authority** | Copies of site-specific Serious Breach Reports submitted to Sponsor-Investigator |[ ] [ ] [ ]   |  |
|  |  | Copies of site-specific Serious Breach Reports submitted to local RGO or Regulatory Authorities, if available |[ ] [ ] [ ]   |  |
|  |  | Copies of all correspondence received from Sponsor-Investigator, local RGO and local Regulatory Authorities relating to submitted Serious Breach Reports. |[ ] [ ] [ ]   |  |
| **3.7** | **Related Correspondence** | Copies of all significant correspondence relating to protocol development, protocol amendments, serious breaches and CAPAs. |[ ] [ ] [ ]   |  |
| **4.0**  | **PARTICIPANT INFORMATION & CONSENT FORMS (GENERIC / MASTER TEMPLATES)** |
| **4.1** | **Site Specific PGICF & PICF Version Tracker** | Site Specific PICF/s Version Tracker * Paper Log or Florence eLog
* One tracker per PICF should be present
 |[ ] [ ] [ ]   |  |
| **4.2** | **Site Specific PGICF & PICFs** | Copy of Site-Specific PGICF and/or PICF* Current and any superseded versions
 |[ ] [ ] [ ]   |  |
|  |  | Copy of any PGICF and/or PICF Translations and Translation Certificates* if applicable
 |[ ] [ ] [ ]   |  |
| **4.3** | **Other Site-Specific Participant Information** | Where applicable, Site-Specific authorised copies of advertisements, participant diaries, telephone scripts, GP Letters, templates, participant newsletters, cards, and questionnaires (e.g., QoL), as applicable to study. |[ ] [ ] [ ]   |  |
| **5.0**  | **REGULATORY DOCUMENTS** |
| **5.1** | **Regulatory Authorisation or Acknowledgement** | Copy of the CTN/CTX Authorisation/ Acknowledgement from the TGA* If applicable
 |[ ] [ ] [ ]   |  |
|  |  | Applicable International Regulatory Authorisation/s from other Regulatory Agencies/Competent Authorities* If applicable
 |[ ] [ ] [ ]   |  |
|  |  | Copies of any significant communication to and from Regulatory Agencies/Competent Authorities, as applicable. |[ ] [ ] [ ]   |  |
| **5.2** | **Supplementary Documents:*** Form FDA 3454; Financial Disclosure
* Form FDA 1572; Statement of Investigator Form
 | Copies of Financial Disclosure Form (FDA 3454 Form), if applicable * Completed and signed by Site Principal Investigator
 |[ ] [ ] [ ]   |  |
|  |  | Copies of Statement of Investigator Form (FDA 1572 Form), if applicable * Completed and signed by Site Principal Investigator
 |[ ] [ ] [ ]   |  |
| **5.3** | **Site Green Light Approval form(s)** | Copy of the completed Site-Specific Green Light Approval Form |[ ] [ ] [ ]   |  |
| **6.0** | **ETHICS COMMITTEE** |
| **6.1** | **Ethics Committee Approval Letters, Certificates and Acknowledgements** | Copy of the Initial Ethics Committee Approval Letter |[ ] [ ] [ ]   |  |
|  |  | Copies of any subsequent Amendmentapprovals/acknowledgement from the Ethics Committee* If applicable
 |[ ] [ ] [ ]   |  |
|  |  | Copies of Ethics Approval Letters/ Acknowledgements relating to ALL other project submissions* If applicable
 |[ ] [ ] [ ]   |  |
| **6.2** | **Ethics Submission Documentation** * **Initial & Amendments**
* **Including responses to HREC queries**
 | Copy of the complete Initial Ethics application relating to the original Protocol/PICF/IB etc, including a copy of the HREA/ethics application |[ ] [ ] [ ]   |  |
|  |  | Copies of the Responses to HREC Queries* If applicable
 |[ ] [ ] [ ]   |  |
|  |  | Copies of complete Protocol Amendments submitted to Ethics, including supporting ERM documentation* If applicable
 |[ ] [ ] [ ]   |  |
|  |  | Copies of all additional Amendments or Project Notifications submitted to Ethics, including supporting ERM documentation.* If applicable
 |[ ] [ ] [ ]   |  |
| **6.3** | **Ethics Committee Composition, Constitution & Statement of Compliance** | Copy of the reviewing Ethics Committee Composition and Statement of Compliance of EC/HREC/IRB, as applicable. |[ ] [ ] [ ]   |  |
| **6.4** | **Annual Project Progress Reports and Final Project Report** | Copies of all Annual Project Progress Reports submitted to Ethics, including supporting ERM documentation |[ ] [ ] [ ]   |  |
|  |  | Copy of the Final Project Progress Report submitted to Ethics, including supporting ERM documentation* If applicable
 |[ ] [ ] [ ]   |  |
|  |  | Copies of any Acknowledgment of Receipt of Annual and Final Progress Reports by EC/HREC/IRB Committee* If applicable
 |[ ] [ ] [ ]   |  |
| **6.5** | **Related Correspondence** | Copies of all significant correspondence to and from the Ethics Committee regarding initial and subsequent submissions. |[ ] [ ] [ ]   |  |
| **7.0** | **RESEARCH GOVERNANCE OFFICE (RGO), IF APPLICABLE** |
| **7.1** | **Governance Authorisation Letters** | Copy of the Initial RGO Approval Letter* If applicable

Copy of any subsequent Amendment approvals from RGO * As applicable
 |[ ] [ ] [ ]   |  |
| **7.2** | **RGO Submission Documents**  | Copies of all local RGO Submissions and Application documents including any responses to local RGO questions/queries* If applicable
 |[ ] [ ] [ ]   |  |
| **7.3** | **Annual Project Progress Reports &****Final Project Report**- Including Acknowledgement of Receipt | Copies of Annual Progress Reports submitted to local RGO, or equivalent* If applicable
 |[ ] [ ] [ ]   |  |
|  |  | Copies of the Final Project Report submitted to local RGO, or equivalent * If applicable
 |[ ] [ ] [ ]   |  |
|  |  | Copies of the Acknowledgment of Receipt of Annual and Final Project Reports by local RGO* If applicable
 |[ ] [ ] [ ]   |  |
| **7.4** | **Related Correspondence*** To and from RGO
 | Copies of all significant correspondence to and from the RGO regarding initial and subsequent submissions |[ ] [ ] [ ]   |  |
| **8.0**  | **STUDY-SPECIFIC PROCEDURES/SOPS**  |
| **8.1** | **MoP and SOP’s** | Copy of the site-specific Manual of Procedures Document* If applicable
 |[ ] [ ] [ ]   |  |
|  |  | Copy of any site-specific trial related SOPs and/or associated documents* If applicable
 |[ ] [ ] [ ]   |  |
| **9.0**  | **SITE INITIATION** |
| **9.1** | **Site Initiation Meeting Documentation** | Copy of the Essential Documents required Prior to Site Activation Request Letter |[ ] [ ] [ ]   |  |
|  |  | Copy of the Site Initiation Booking Confirmation Letter |[ ] [ ] [ ]   |  |
|  |  | Copy of the Site-Specific Site Initiation Agenda |[ ] [ ] [ ]   |  |
|  |  | Copy of the Site-Specific Site Initiation Presentation Slide Set |[ ] [ ] [ ]   |  |
|  |  | Copy of the Site Initiation Attendance Log* Completed and signed by all those that attended the SIV
 |[ ] [ ] [ ]   |  |
| **9.2** | **Site Initiation Follow-Up Letter** | Copy of the Site Initiation Follow-Up Letter to the Site |[ ] [ ] [ ]   |  |
| **9.3** | **Site Activation Documentation/ Letter** | Copy of the official Notification of Site Activation Letter to the Site |[ ] [ ] [ ]   |  |
| **10.0**  | **SITE TRAINING** |
| **10.1** | **Investigator Meeting** | Copy of the Investigator Meeting Presentation Slide Set |[ ] [ ] [ ]   |  |
|  |  | Copy of the Investigator Meeting Attendance Log |[ ] [ ] [ ]   |  |
| **10.2** | **Other Presentations** | Copies of all other Site-Specific presentations delivered |[ ] [ ] [ ]   |  |
| **10.3** | **Site-Specific Training Logs** | Copy of the Site-Specific Training Log |[ ] [ ] [ ]   |  |
|  |  | Copies of other Training Attestation Forms* If applicable
 |[ ] [ ] [ ]   |  |
| **11.0** | **PARTICIPANT RECRUITMENT** |
| **11.1** | **Consent, Screening & Enrolment Log** | Copy of the Site-Specific Consent, Screening & Enrolment Log |[ ] [ ] [ ]   |  |
| **11.2** | **Related Correspondence** | Copies of all significant correspondence to and from the site regarding participant recruitment |[ ] [ ] [ ]   |  |
| **12.0** | **PARTICIPANT RANDOMISATION AND REGISTRATION PROCEDURES** |
| **12.1** | **Records of Unblinding** **- Site Participants** | Copies of all local participant records of unblinding during study conduct and reasons for unblinding, as applicable |[ ] [ ] [ ]   |  |
| **12.2** | **Related Correspondence** | All significant correspondence relating to participant randomisation and unblinding procedures, to and from the Sponsor |[ ] [ ] [ ]   |  |
| **13.0**  | **DATA MANAGEMENT – FORMS & PROCEDURES** |
| **13.1** | **Completed Electronic Data Capture (EDC) System Application Forms** | Copies of EDC Account Application Forms – completed and signed forms from key research personnel requiring database access at the participating site. |[ ] [ ] [ ]   |  |
| **13.2** | **Source Document Plan** | Copy of the Site-Specific Source Document Plan – completed, signed and dated by the Site Principal Investigator. |[ ] [ ] [ ]   |  |
| **13.3** | **Related Correspondence** | All significant correspondence relating to data management. |[ ] [ ] [ ]   |  |
| **14.0**  | **SAFETY MONITORING & REPORTING** |
| **14.1** | **Copy of Completed Site Expedited Safety Report Forms and associated correspondence sent to Sponsor*** **All SAEs, suspected SUSARs and USMs**
 | Copies of completed Initial SAE Report Forms* Completed, signed and dated by the Site Principal Investigator and sent to Sponsor.
 |[ ] [ ] [ ]   |  |
|  |  | Copies of completed Follow-Up SAE Report Forms * Completed, signed and dated by the Site Principal Investigator and sent to Sponsor
 |[ ] [ ] [ ]   |  |
| **14.2** | **Copy of all Safety Reports sent to the local Research Governance Office (RGO) or regulatory Authority*** **If applicable**
 | Copies of Site-Specific safety reports/notifications submitted to local RGO or Regulatory Authorities, if available |[ ] [ ] [ ]   |  |
|  |  | Copies of all correspondence received from local RGO or Regulatory Authorities relating to submitted safety reports/notifications |[ ] [ ] [ ]   |  |
| **14.3** | **On-Site Procedure for Unblinding in either*** **The case of a medical emergency**
* **For safety reporting purposes**
 | Copy of the Site-Specific Emergency Procedures for Unblinding Site Manual, if applicable |[ ] [ ] [ ]   |  |
| **14.4** | **Other Related Correspondence** | Copies of “Dear Investigator Letters (DIL)”, Safety Memo’s, Safety Notifications, SUSAR 6-Monthly line listings received from pharmaceutical companies, with or without acknowledgement of receipts, and sent to local RGO or Regulatory Authorities, as applicable |[ ] [ ] [ ]   |  |
|  |  | All other significant correspondence relating to safety monitoring and reporting requirements, to and from the site |[ ] [ ] [ ]   |  |
| **15.0**  | **STUDY QUALITY ASSURANCE, MONITORING, AUDITS & INSPECTIONS** |
| **15.1** | **Pre-Trial Visit Reports, Attendance and Correspondence** * **If applicable**
 | Pre-Trial Site Visit Checklist* Completed by Trial Coordinator
 |[ ] [ ] [ ]   |  |
|  |  | Copy of the Pre-Trial Site Visit Report to the Site |[ ] [ ] [ ]   |  |
|  |  | Copy of the Pre-Trial Site Visit Attendance Log  |[ ] [ ] [ ]   |  |
|  |  | Copies of all significant correspondence relating to pre-trial site visits to and from the site |[ ] [ ] [ ]   |  |
| **15.2** | **Site Monitoring and Visit Log** | Copy of the Site Monitoring and Visit Log * Recording all site visits completed, whether Site Monitoring or Site Audit visits have been performed
 |[ ] [ ] [ ]   |  |
| **15.3** | **Monitoring Visit Reports and Remote Monitoring Reports** | Copies of all Monitoring Visit Reports (either from on-site or remote monitoring visits) |[ ] [ ] [ ]   |  |
| **15.4** | **Monitoring Visit Correspondence** * **Including Feedback to site**
 | Copies of all Monitoring Visit Confirmation Letters to the Site |[ ] [ ] [ ]   |  |
|  |  | Copies of all Monitoring Visit Follow Up Letters to the Site |[ ] [ ] [ ]   |  |
| **15.5** | **Trial Close-Out** | Copy of the Trial Close-Out Report to the Site, if applicable |[ ] [ ] [ ]   |  |
|  |  | Copy of the Trial Close-Out Letter |[ ] [ ] [ ]   |  |
|  |  | Copy of the Investigator Agreement to Archive Letter, signed by the Site Principal Investigator |[ ] [ ] [ ]   |  |
|  |  | Copies of all significant correspondence relating to trial close-out activities to and from the Sponsor. |[ ] [ ] [ ]   |  |
| **15.6** | **Local RGO Audits** | Copies of all reports resulting from any Audits occurring at site, if available |[ ] [ ] [ ]   |  |
|  |  | Copies of any correspondence related to Audits occurring at site, if available.  |[ ] [ ] [ ]   |  |
| **15.7** | **Regulatory Inspection Reports** | Copies of all reports resulting from Regulatory Inspection occurring at site, if available |[ ] [ ] [ ]   |  |
|  |  | Copies of any correspondence related to Regulatory Inspections occurring at site, if available. |[ ] [ ] [ ]   |  |
| **16.0**  | **LOCAL LABORATORY** |
| **16.1** | **Local Lab Certificates of Accreditation** * **If applicable**
 | Copy of the Local Site Lab Accreditation – i.e. NATA Accreditation Certificate |[ ] [ ] [ ]   |  |
| **16.2** | **Local Lab Reference Ranges** * **If applicable**
 | Copy of the Site-Specific Local Lab Reference Ranges |[ ] [ ] [ ]   |  |
| **16.3** | **Biospecimen Collection Log** * **If applicable**
 | Copy of the Biospecimen Collection Log, completed and up to date with relevant sample collection details. |[ ] [ ] [ ]   |  |
| **16.4** | **Biospecimen Shipment Receipt Tracking** | Copies of any courier shipping documents, invoices, receipts, custom declarations, consignment notes, import permits from site to the Central Laboratory and/or Sponsor.  |[ ] [ ] [ ]   |  |
| **16.5** | **Biospecimen Storage Monitoring Documentation** * **If applicable**
 | Copies of any Site-Specific documentation relating to the monitoring of biospecimen storage at site |[ ] [ ] [ ]   |  |
| **16.6** | **Related Correspondence** | Copies of all significant correspondence to and from the Central Lab or relating to the Biospecimen Research aspects of the study. |[ ] [ ] [ ]   |  |
| **17.0**  | **SUPPLIES/SHIPPING RECORDS** |
| **17.1** | **Documentation relating to provision of Study Supplies** | Copies of any correspondence or documentation regarding the provision of study supplies to site |[ ] [ ] [ ]   |  |
|  |  | Copies of any receipts of study supplies to site* If applicable
 |[ ] [ ] [ ]   |  |
| **18.0** | **LEGAL DOCUMENTATION** |
| **18.1** | **Fully Executed Clinical Trial Research Agreement (CTRA)** | Copy of the fully executed Clinical Trial Agreement between the Participating Site and the Sponsor. |[ ] [ ] [ ]   |  |
| **18.2** | **Other Agreements as applicable** | Copies of any of the following fully executed Site-Specific agreements as applicable to the trial:* Material Transfer Agreements (MTA)
* Data Sharing Agreements (DSA)
* Insurance/Indemnity, as applicable
* Expressions of Interest (EoI)
 |[ ] [ ] [ ]   |  |
| **18.3** | **Relevant Correspondence** | Copies of all significant correspondence relating to any Agreements pertaining to the study. |[ ] [ ] [ ]   |  |
| **19.0**  | **FINANCE DOCUMENTATION** |
| **19.1** | **Invoices and Receipts** | Copies of relevant Site-Specific invoices and receipts pertaining to the study, including per patient payments. |[ ] [ ] [ ]   |  |
| **19.2** | **Related Correspondence** | Copies of all significant correspondence regarding the study budget, invoice tracking, per patient payments, etc. |[ ] [ ] [ ]   |  |
| **20.0**  | **OTHER COMMUNICATION** |
| **20.1** | **Newsletters to Sites** | Copies of Newsletters from the sponsor to Participating Sites |[ ] [ ] [ ]   |  |
| **20.2** | **Other General Correspondence** | Copies of all other significant general correspondence |[ ] [ ] [ ]   |  |
| **21.0**  | **ARCHIVING** |
| **21.1** | **Archiving Details** | Copy of the Investigator Agreement to Archive Trial Documents Form * Completed and signed by Site Investigator and Sponsor
 |[ ] [ ] [ ]   |  |
| **21.2** | **Related Correspondence** | Copies of all significant correspondence regarding trial archiving to and from the Participating Site |[ ] [ ] [ ]   |  |
| **22.0** | **INVESTIGATIONAL PRODUCT (FOR DRUG AND DEVICE TRIALS ONLY)***NOTE: In most cases, all IP related activities at site will have been delegated to a Central Pharmacy or to the Site Pharmacy Department – hence, the relevant documents listed below may be located in a Central or Participating Site Pharmacy folder, and not provided to the Sponsor until the end of the trial.*  |
| **22.1** | **Documentation of IP Shipment** | Copies of Shipping Records of IP to the Site * If available
 |[ ] [ ] [ ]   |  |
| **22.2** | **Documentation of IP Dispensing, Accountability and Inventory** | Copies of Site-Specific Bulk Drug Accountability Log |[ ] [ ] [ ]   |  |
|  |  | Copies of Site-Specific Individual Drug Accountability Log |[ ] [ ] [ ]   |  |
| **22.3** | **Documentation of IP Storage Monitoring** | Copies of any Site-Specific documentation relating to the monitoring of IP Storage and IP Storage Facilities at the participating site |[ ] [ ] [ ]   |  |
| **22.4** | **Documentation of Central IP:*** **Quarantines**
* **Returns**
* **Destructions/Drug Destruction Form**
 | Copies of any completed Site-Specific Drug Destruction Forms |[ ] [ ] [ ]   |  |
|  |  | Copies of any Site-Specific IP Deviations (i.e. temperature excursions, IP complaints, IP quarantines) and associated forms, as completed by the site |[ ] [ ] [ ]   |  |
|  |  | Copies of any IP Returns and/or Drug Destruction Forms relating to any unused IP at the end of the study, as completed by the site |[ ] [ ] [ ]   |  |
| **22.5** | **Related Correspondence** | Copies of all significant correspondence relating to the Investigational Product/s. |[ ] [ ] [ ]   |  |

**Peer Review Sign-Off:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Peer Reviewer Name:****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Date Peer Review Completed** **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_ | **Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Follow Up Required**[ ]  Yes [ ]  No |

**Completed QA Review Forms must be returned to the nominated Research Team Member for actioning of any follow-up items/CAPAs.**

**Research Team Review and Sign-Off:**

|  |  |
| --- | --- |
| **Name of Research Team Member Responsible for TMF/SIF:** |  |
| **Date Corrective Action or Response Completed**  | Date: \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_ |
| **Signature:** |  |

**MCRI Sponsorship Committee Review and Sign-Off:**

|  |  |  |
| --- | --- | --- |
| **Sponsorship Committee Representative Name:****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_ | **Sponsorship Committee****Representative Signature:\_\_\_\_\_\_\_\_\_\_\_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |