**Trial Master File (TMF) 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> |
|  | | | |
| **Reason for Review** | Routine Annual  Ad hoc; Sp*ecify:\_\_\_\_\_\_\_\_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **TMF 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 Master 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 TMF Folders Not Subject or Not Applicable for Review** | Folders and/or documents which are NOT subject to this TMF 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 Trial Master File (TMF) 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: TMF QA Review Checklist**

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

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

| **FOLDER/ SECTION** | **TITLE** | **DOCUMENTS** | **PRESENT IN FILE?** | | | **PEER REVIEWER COMMENTS including any**  **Follow Up Required** | **CORRECTIVE ACTION or RESPONSE**  Completed by Research Team Member Responsible for TMF/SIF |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **YES** | **NO** | **N/A** |
| **1.0** | **CENTRAL TRIAL COORDINATING TEAM** | | | | | | |
| **1.1** | **Contact List** | Copy of the Contact List from the Central Trial Coordinating Team |  |  |  |  |  |
| **1.2** | **Signature and Delegation of Duties Log** | Copy of the Signature and Delegation of Duties Log signed by all members of the Central Trial Coordinating Team |  |  |  |  |  |
| **1.3** | **CVs** | Original CV of Sponsor-Investigator   * signed and dated within last two years |  |  |  |  |  |
| Original CV of Trial Manager/Coordinator   * signed and dated within last two years |  |  |  |  |  |
| Original CV of Statistician   * signed and dated within last two years |  |  |  |  |  |
| Original CV of Lead Data Manager   * signed and dated within last two years |  |  |  |  |  |
| Copies of Medical Licenses (if applicable) |  |  |  |  |  |
| **1.3.1** | **Other CVs** | Original CV from all Site staff involved in the trial   * signed and dated within last two years |  |  |  |  |  |
| Copies of Medical / AHPRA Licenses   * if applicable |  |  |  |  |  |
| **1.4** | **GCP Training Certificates** | Copy of the GCP Training Certificate from Sponsor-Investigator |  |  |  |  |  |
| Copy of the GCP Training Certificate from Trial Manager/Coordinator |  |  |  |  |  |
| Copy of the GCP Training Certificate from Statistician |  |  |  |  |  |
| Copy of the GCP Training Certificate from Lead Data Manager |  |  |  |  |  |
| **1.4.1** | **Other GCP Training Certificates** | Copies of GCP Training Certificate from other Site staff involved in the trial |  |  |  |  |  |
| **1.5** | **Training Certificates** | * Copy of the Training Log signed by all members of the Central Trial Coordinating Team * Copies of other training certificates from key research team personnel from the Central Trial Coordinating Team |  |  |  |  |  |
| **1.5.1** | **Other Training Certificates** | Copies of other training certificates from key research team personnel from the Central Trial Coordinating Team |  |  |  |  |  |
| **1.6** | **Wet Ink Signatures** | Wet ink signature page from all key research team personnel from the Central Trial Coordinating Team who digitally sign documents using Florence eBinders |  |  |  |  |  |
| **1.6.1** | **Other Wet Ink Signatures**   * Only applicable if not using a wet ink signature log | Copies of the Wet Ink Signature Page from all other key research team personnel from the Central Trial Coordinating Team. |  |  |  |  |  |
| **2.0** | **PROJECT MANAGEMENT** | | | | | | |
| **2.1** | **Trial Start-Up Checklist** | Copy of the Trial Start-Up Checklist |  |  |  |  |  |
| **2.2** | **Site Selection Documentation** | Where applicable, copy of the CRO/Vendor Selection Criteria Form – completed and signed |  |  |  |  |  |
| Where applicable, copy of the Drug Distribution and Storage Facility Questionnaire – completed with details of any follow-up actions clearly documented |  |  |  |  |  |
| Where applicable, copy of the Pre-Trial Site Visit Agenda |  |  |  |  |  |
| Where applicable, copy of the Pre-Trial Site Visit Checklist – completed to reflect visit |  |  |  |  |  |
| Where applicable, copy of the Pre-Trial Site Selection Visit Report – completed and reviewed |  |  |  |  |  |
| Copy of the Site Feasibility Questionnaire Template |  |  |  |  |  |
| Copies of any Site Feasibility Questionnaire – completed by potential sites |  |  |  |  |  |
| Copies of any Site Feasibility Assessments – completed on Potential sites |  |  |  |  |  |
| Where applicable, Clinical CRO/ Vendor Assessment Form – completed |  |  |  |  |  |
| Where applicable, Vendor Assessment Form – completed with details of any follow-up actions clearly documented |  |  |  |  |  |
| Where applicable, CRO Vendor Assessment Report – completed post assessment |  |  |  |  |  |
| Where applicable, Vendor Acceptance/Rejection Letter |  |  |  |  |  |
| Where applicable, Study Vendor Log – maintained by Trial Coordinator throughout study |  |  |  |  |  |
| Copies of any significant correspondence relating to Site Feasibility and Site Selection |  |  |  |  |  |
| Copy of the Site Feasibility Tracker |  |  |  |  |  |
| **2.3** | **Administration** | Copy of the Roles and Responsibilities (R&R) Matrix for the Central Trial Coordinating Centre Team, and where applicable and other R&R Matrices |  |  |  |  |  |
| Copies of any significant correspondence |  |  |  |  |  |
| **2.4** | **Trial Meeting Agenda/Minutes, Notes, etc.** | Copies of all Trial meeting agendas and minutes of every meeting with the Sponsor-Investigator and/or research team |  |  |  |  |  |
| **2.5** | **Significant Team Correspondence & Communication including Emails, etc.** | Copies of all other significant correspondence |  |  |  |  |  |
| **3.0** | **PROTOCOL/PROTOCOL AMENDMENTS** | | | | | | |
| **3.1** | **Protocol Version Tracker** | Copy of the Protocol Version Tracker |  |  |  |  |  |
| **3.2** | **Current HREC Approved Study Protocol and Signed Protocol Signature Page / Investigator Agreement Page** | Copy of the Study Protocol   * Current HREC Approved and signed final copy |  |  |  |  |  |
| Copy of the signed Protocol Signature Page   * Signed by the Sponsor-Investigator/CPI or Sponsor Representative |  |  |  |  |  |
| Copies of previously signed Protocol Signature Pages from superseded protocols |  |  |  |  |  |
| **3.3** | **Protocol – Evidence of review and approval by Sponsor** | Copy of the Protocol Review Checklist – Study Coordinator, as completed by the Trial/Study Coordinator |  |  |  |  |  |
| Copy of the Protocol Review Checklist – Statistician, as completed by the Trial Statistician |  |  |  |  |  |
| Copy of the Protocol Approval and Sign-Off Form – signed by Trial Coordinator, Statistician and Sponsor Investigator prior to HREC submission |  |  |  |  |  |
| **3.4** | **Peer Review – Evidence of Review** | Evidence of Peer Review |  |  |  |  |  |
| **3.5** | **Non-Compliance Reports and Central Non-Compliance Log** | Copy of the Master Non-Compliance Report Form |  |  |  |  |  |
| Copy of the Master Non-Compliance Review Form |  |  |  |  |  |
| Copy of the Central Non-Compliance Log |  |  |  |  |  |
| **3.6** | **Sponsor-Level Serious Breaches and CAPAs** | Copies of any Sponsor-level Corrective and Preventive Action Plans (CAPA) |  |  |  |  |  |
| Copies of any Sponsor-level Corrective and Preventive Action Plan (CAPA) Reviews |  |  |  |  |  |
| **3.7** | **Copy of all Serious Breach reports to Sponsor-Investigator/HREC or Regulatory Authorities, if applicable** | Copies of all Serious Breach Reports submitted to Ethics Committees   * including supporting ERM documentation and any return acknowledgment |  |  |  |  |  |
| Copies of all Serious Breach Reports submitted to Regulatory Authorities   * and any return acknowledgment |  |  |  |  |  |
| **3.8** | **Related Correspondence** | Copies of all significant correspondence relating to protocol development, protocol amendments, sponsor-level serious breaches and CAPAs. |  |  |  |  |  |
| **4.0** | **PARTICIPANT INFORMATION & CONSENT FORMS** (Generic / Master templates) | | | | | | |
| **4.1** | **PGICF & PICF Version Tracker** | Copy of the PGICF & PICF Version Tracker |  |  |  |  |  |
| **4.2** | **Master PGICF & PICF –** Current HREC Approved Version(s) | Copies of the Template Master PGICF & PICF/s |  |  |  |  |  |
| **4.3** | **Other Participant Information** | Copies of other approved Participant Information |  |  |  |  |  |
| **4.4** | **PGICF & PICF – Evidence of Review and Approval** | Copy of the PGICF / PICF Review Checklist – Study Coordinator |  |  |  |  |  |
| Copy of the PGICF / PICF Approval and Sign-Off Form   * Signed by Trial Coordinator and Sponsor-Investigator/CPI. |  |  |  |  |  |
| **5.0** | **REGULATORY DOCUMENTS** | | | | | | |
| **5.1** | **Site Green Light Approval form(s)** | Copy of the Master Site Green Light Approval Form |  |  |  |  |  |
| **5.2** | **TGA Acknowledgement Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX)** | Copy of the CTN Acknowledgement listing all participating sites |  |  |  |  |  |
| Copy of the CTX Acknowledgement listing all participating sites |  |  |  |  |  |
| **5.3** | **CTN/CTX Submission(s)** | Copy of the electronic CTN Submission to the TGA listing participating sites |  |  |  |  |  |
| Copy of the TGA CTN Invoice, if available |  |  |  |  |  |
| Copy of the Proof of CTN Payment, if available |  |  |  |  |  |
| **5.4** | **Other TGA Correspondence** | Copies of all significant correspondence to and from the TGA |  |  |  |  |  |
| **5.5** | **International Regulatory Submissions**  *(e.g. MHRA, HPRA, FDA, etc)* | Copies of the relevant International Regulatory Submissions (e.g. IND applications), if applicable |  |  |  |  |  |
| **5.6** | **International Regulatory Approvals** | Copies of International Regulatory Certificates of Approvals, if applicable |  |  |  |  |  |
| **5.7** | **International Regulatory Related Correspondence** | Copies of all significant correspondence to and from any Regulatory Agency, if applicable |  |  |  |  |  |
| **5.8** | **Supplementary FDA Documents** | Copies of all signed Financial Disclosure Forms (FDA 3454 Form) from relevant members of the Research Teams, if applicable |  |  |  |  |  |
| Copies of all signed Statement of Investigator Forms (FDA 1572 Form) from all relevant members of the Research Teams, if applicable |  |  |  |  |  |
| **6.0** | **SPONSORSHIP** | | | | | | |
| **6.1** | **Sponsor Authorisation Letter** | Copy of the MCRI Certificate of Sponsorship |  |  |  |  |  |
| Subsequent copies of MCRI Certificates of Sponsorship |  |  |  |  |  |
| **6.2** | **Completed Risk Assessment and Risk Management Tool** | Copy of the completed MCRI Sponsorship Application including completed Risk Management Table |  |  |  |  |  |
| Copies of any subsequent submissions to the MCRI Sponsorship Committee |  |  |  |  |  |
| **6.3** | **Related Correspondence and Meeting Minutes** | Copies of all significant correspondence to and from the Sponsor regarding initial and subsequent submissions, including meeting minutes. |  |  |  |  |  |
| **7.0** | **ETHICS COMMITTEE** | | | | | | |
| **7.1** | **Ethics Committee Approval Letters, Certificates and Acknowledgements** | Copy of the Initial Ethics Committee Approval Letter |  |  |  |  |  |
| Copies of all HREC Letters/Acknowledgements relating to the original Protocol/PICF/IB etc |  |  |  |  |  |
| Copies of all subsequent Amendment approvals/acknowledgement from the Ethics Committee |  |  |  |  |  |
| Copies of all Ethics Approval Letters/ Acknowledgements relating to ALL other project submissions. |  |  |  |  |  |
| **7.2** | **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 |  |  |  |  |  |
| Copy of the Responses to HREC Queries, if applicable |  |  |  |  |  |
| Copy of any Protocol Amendments submitted to Ethics Committees, including supporting ERM documentation |  |  |  |  |  |
| Copies of all additional Amendments or Project Notifications submitted to Ethics Committees, including supporting ERM documentation. |  |  |  |  |  |
| **7.3** | **Ethics Committee Composition, Constitution & Statement of Compliance** | Copy of the Ethics Committee Composition or where applicable, a copy of the Statement of Compliance of Leading EC |  |  |  |  |  |
| **7.4** | **Annual Project Progress Reports and Final Project Report** | Copies of all Annual Project Progress Reports submitted to Ethics Committees, including supporting ERM documentation |  |  |  |  |  |
| Copy of the Final Project Progress Report submitted to Ethics Committees, including supporting ERM documentation |  |  |  |  |  |
| **7.5** | **Related Correspondence** | Copies of all significant correspondence to and from the Ethics Committee regarding initial and subsequent submissions. |  |  |  |  |  |
| **8.0** | **STUDY-SPECIFIC PROCEDURES/SOPS** (Applicable to either the Central Trial Coordination Team or all Sites) | | | | | | |
| **8.1** | **MoP and SoP’s** | Copy of the Manual of Procedures (MoP) Document |  |  |  |  |  |
| Any Manual of Procedures associated documents, as applicable:  - Study Specific SOPs  - Imaging Manual  - Imaging Charter  - Central Review Manual  - Nuclear Review Manual  - Ophthalmology Manual  - Radiotherapy Manual  - Any study-specific SOP associated documents |  |  |  |  |  |
| **9.0** | **SITE TRAINING** | | | | | | |
| **9.1** | **SIV Presentation** | Copy of the Site Initiation Visit Presentation slide set   * Generic Master version |  |  |  |  |  |
| Copy of the Site Initiation Agenda   * Generic Master version |  |  |  |  |  |
| Copy of the Site Initiation Booking Letter   * Generic Master version |  |  |  |  |  |
| Copy of the Essential Document Request Letter   * Generic Master version |  |  |  |  |  |
| Copy of the Site Initiation Attendance Log   * Generic Master version |  |  |  |  |  |
| Copy of the Site Initiation Follow Up letter   * Generic Master version |  |  |  |  |  |
| Copy of the Site Activation Letter   * Generic Master version |  |  |  |  |  |
| **9.2** | **Investigator Meeting** | Copy of the Investigator Meeting Presentation slide set |  |  |  |  |  |
| Copy of the Investigator Meeting Attendance Log   * Completed and signed by all attendees |  |  |  |  |  |
| **9.3** | **Other Presentations** | Copies of other presentations than the generic Master Site Initiation Visit presentation used for site training purposes here.   * E.g. For site re-training, training presentations on the study database etc. |  |  |  |  |  |
| **9.4** | **Training Logs** | Copy of the Study-Specific Training Log   * Generic Master version |  |  |  |  |  |
| Copies of other Training Attestation Forms, if applicable   * Generic Master versions |  |  |  |  |  |
| **9.5** | **Other Training Resources** | Copies of other site-specific training resources/ materials provided to sites. |  |  |  |  |  |
| **10.0** | **PARTICIPANT RECRUITMENT** | | | | | | |
| **10.1** | **Pre-Screening Log Template** | Copy of the Pre-Screening Log   * Generic Master version |  |  |  |  |  |
| **10.2** | **Consent, Screening & Enrolment Log Template** | Copy of the Consent, Screening & Enrolment Log   * Generic Master version |  |  |  |  |  |
| **10.3** | **Participant ID Log Template** | Copy of the Participant ID Log   * Generic Master version |  |  |  |  |  |
| **11.0** | **PARTICIPANT RANDOMISATION AND REGISTRATION PROCEDURES** | | | | | | |
| **11.1** | **Randomisation Manual or Participant Registration Procedure** | Copy of the Randomisation Manual and/or Randomisation Plan or Participant Registration Procedures |  |  |  |  |  |
| **11.2** | **Records of Unblinding**   * all participants | Copies of all records of Unblinding during study conduct including reasons for unblinding |  |  |  |  |  |
| **11.3** | **Related Correspondence** | Copies of all significant correspondence relating to participant randomisation and unblinding procedures. |  |  |  |  |  |
| **12.0** | **DATA MANAGEMENT – FORMS & PROCEDURES** | | | | | | |
| **12.1** | **Blank Sample CRF** | Copy of the annotated CRFs (for eCRFs) or Blank CRFs (for Paper CRFs) |  |  |  |  |  |
| **12.2** | **CRF Completion Guidelines** | Copy of the CRF Completion Guidelines |  |  |  |  |  |
| **12.3** | **Trial-Specific Data Management Plan** | Copy of the Data Management Plan |  |  |  |  |  |
| Copy of the Data Sharing Plan |  |  |  |  |  |
| Copy of the Source Document Plan   * Generic Master Version |  |  |  |  |  |
| Copy of the Data Validation Plan |  |  |  |  |  |
| Copy of the Medical Review Plan and associated Review Forms   * Template review forms only |  |  |  |  |  |
| Copy of any other Data Review Committees and/or Plans. |  |  |  |  |  |
| **12.4** | **Database Management Documentation**   * DB Specification * DB Testing * Database Version Tracker | Copy of the Database Specifications |  |  |  |  |  |
| Copy of the Database Review and Testing Log |  |  |  |  |  |
| Copy of the Database Version Tracking Log   * To be completed by the Database Manager, if applicable or Trial Coordinator |  |  |  |  |  |
| Copy of any Transfer of Data Forms |  |  |  |  |  |
| **12.5** | **Trial Database Design Approval Form** | Copy of the Database Approval Form   * To be completed by the Database Manager, if applicable or Trial Coordinator * Signed by Database Manager, if applicable, Trial Coordinator, Statistician and Sponsor-Investigator |  |  |  |  |  |
| **12.6** | **Electronic Data Capture (EDC) System Application Form - Template** | Copy of the Electronic Data Capture (EDC) System Account Application Form   * Generic Master version |  |  |  |  |  |
| **12.7** | **Completed Electronic Data Capture (EDC) System Application Forms** | Copy of completed Electronic Data Capture (EDC) System Account Application Form   * Completed and signed forms from key research personnel |  |  |  |  |  |
| **12.8** | **Related Correspondence** | Copies of all significant correspondence relating to data management. |  |  |  |  |  |
| **13.0** | **SAFETY MONITORING & REPORTING (ALL SITES)**  *Please note that the RSI is filed in section 24.1* | | | | | | |
| **13.1** | **Blank Expedited Safety Report Form Template**  (i.e. SAE Form) and Safety Reporting Guidelines | Copy of the Expedited Safety (SAE) Report Form Template   * Generic Master Version |  |  |  |  |  |
| Copy of the Safety Event (SAE) Review Form Template­   * Generic Master Version |  |  |  |  |  |
| Copy of the Safety Monitoring Plan­ |  |  |  |  |  |
| Copy of the Safety Reporting Guidelines for Sites Example |  |  |  |  |  |
| Copy of the Expedited Safety (SAE) Report Coversheet Template |  |  |  |  |  |
| Copy of the Expedited Safety (SAE) Report Completion Instructions |  |  |  |  |  |
| Copy of the Expedited Pregnancy Coversheet (for drug trials, if applicable) |  |  |  |  |  |
| Copy of the Expedited Pregnancy Report Form – (for drug trials, if applicable)   * Generic Master Version |  |  |  |  |  |
| Copy of the Expedited Pregnancy Report Completion Instructions – (for drug trials, if applicable) |  |  |  |  |  |
| Copy of the Instructions for Medical Monitors |  |  |  |  |  |
| Copy of the SAE Form for Non-MCRI-Sponsored Studies   * Generic Master Version |  |  |  |  |  |
| Copy of the Review of Safety Events: Instructions for Trial Coordinator |  |  |  |  |  |
| **13.2** | **Copy of Completed Expedited Safety Report Forms**   * From all SAEs, suspected SUSARs and USMs * Associated correspondence from all Sites | Completed Expedited Safety (SAE) Report Forms  - Completed, signed, and dated by Site PIs) |  |  |  |  |  |
| Completed Safety Event (SAE) Review Form  - Completed, signed, and dated by Medical Monitor |  |  |  |  |  |
| **13.3** | **Copy of all Safety Reports sent to HREC, TGA, Regulatory Authorities and Participating Sites.**  i.e. SUSARs, SSIs, USMs, Annual Safety Reports, etc. | Copies of Annual Safety Reports submitted to Ethics Committees, including supporting ERM documentation |  |  |  |  |  |
| Copies of SUSARs/URSAEs, SSIs and USMs submitted to Ethics Committees, including supporting ERM documentation |  |  |  |  |  |
| Copies of trial SUSARs/URSAEs, SSIs and USMs including evidence that they have been appropriately actioned |  |  |  |  |  |
| Copies of the submission of SUSARs/URSAEs, SSIs and USMs to appropriate regulatory bodies, as applicable, i.e. TGA |  |  |  |  |  |
| Copies of Notification of all trial SUSARs/URSAEs, SSIs and USMs sent to participating sites |  |  |  |  |  |
| Copies of 6-monthly SUSAR Line-Listing received from Drug Companies, including evidence they have been actioned accordingly   * If applicable |  |  |  |  |  |
| **13.4** | **Copy of all Serious Breach reports to Sponsor-Investigator/HREC or Regulatory Authorities, if applicable** | Copies of all Serious Breach Reports submitted to Ethics Committees, including supporting ERM documentation and any return acknowledgment |  |  |  |  |  |
| Copies of all Serious Breach Reports submitted to Regulatory Authorities any return acknowledgment |  |  |  |  |  |
| **13.5** | **Written Procedure for Unblinding in either:**   * The case of a medical emergency * For safety reporting purposes | Copy of the Emergency Procedures for Unblinding Manual or SOP |  |  |  |  |  |
| **13.6** | **Other related correspondence** | Copies of all significant correspondence relating to safety monitoring and reporting requirements. |  |  |  |  |  |
| **14.0** | **STUDY QUALITY ASSURANCE, MONITORING, AUDITS & INSPECTIONS** | | | | | | |
| **14.1** | **Clinical Monitoring Plan** | Copy of the Clinical Monitoring Plan |  |  |  |  |  |
| Copy of the Risk Assessment and Risk Management Tool for Clinical Trials |  |  |  |  |  |
| Other monitoring associated documents, as applicable |  |  |  |  |  |
| **14.2** | **Clinical Monitoring Plan – Evidence of Review and Approval by Sponsor-Investigator** | Clinical Monitoring Plan Approval and Sign-Off Form   * Signed by Sponsor-Investigator/CPI |  |  |  |  |  |
| **14.3** | **Monitoring Log** | Copy of the Site Monitoring and Visit Log |  |  |  |  |  |
| **14.4** | **Monitoring Visit Reports, including Evidence of Review and Approval by Sponsor/Delegate** | Copy of the SIV Report Template   * Generic Master Version |  |  |  |  |  |
| Copy of the Site Monitoring Visit Report Template   * Generic Master Version |  |  |  |  |  |
| **14.5** | **Related Monitoring Correspondence** | Copies of all significant correspondence relating to site monitoring |  |  |  |  |  |
| **14.6** | **DATA SAFETY MONITORING BOARD (DSMB)** | | | | | | |
| **14.6.1** | **DSMB Charter** | Copy of the DSMB Charter   * Signed by members of the DSMB |  |  |  |  |  |
| **14.6.2** | **Charter – Evidence of Review and Approval by Sponsor-Investigator/CPI** | DSMB Charter Approval and Sign-Off Form   * Signed by the Trial Coordinator, Statistician, Sponsor Investigator, Sponsor Representative, and members of the DSMB |  |  |  |  |  |
| **14.6.3** | **DSMB Meeting Minutes** | Copies of all minutes from DSMB meetings held throughout trial conduct   * Signed by the DSMB Chair) |  |  |  |  |  |
| **14.6.4** | **Related Correspondence** | Copies of all significant correspondence to and from the DSMB and all other DSMB related correspondence |  |  |  |  |  |
| **14.7** | **TRIAL STEERING COMMITTEE (TSC)/TRIAL MANAGEMENT COMMITTEE (TMC)/OTHER COMMITTEES** | | | | | | |
| **14.7.1** | **Steering Committee Charter(s)** | Copy of the Trial Steering Committee (TSC) Charter |  |  |  |  |  |
| **14.7.2** | **Documentation/Approval by Sponsor-Investigator** | Copy of the TSC Charter Approval and Sign-Off Form   * Signed by Trial Coordinator, Statistician and Sponsor Investigator/CPI |  |  |  |  |  |
| **14.7.3** | **Committee Meeting Minutes** | Copies of all minutes from Trial Steering Committee/Other Trial Committee meetings held throughout trial conduct   * Signed by the Committee Chair |  |  |  |  |  |
| **14.8** | **Local Research Governance Office Documentation – all sites:**   * Copy of all Audit Reports | Copies of all Audit Reports sent to Local Research Governance Offices   * If applicable |  |  |  |  |  |
| **14.9** | **Regulatory Inspections:**   * Reports * Related Correspondence | Copies of all Regulatory Inspection Reports |  |  |  |  |  |
| Copies of any correspondence related to Regulatory Inspections |  |  |  |  |  |
| **15.0** | **STATISTICS** | | | | | | |
| **15.1** | **Statistical Analysis Plan (SAP)** | Copy of the Statistical Analysis Plan (SAP) |  |  |  |  |  |
| **15.2** | **Statistical Analysis Plan – Evidence of review and approval from Sponsor-Investigator** | Copy of the Statistical Analysis Plan (SAP) Approval and Sign-Off Form   * Signed by Statistician and Sponsor- Investigator/CPI |  |  |  |  |  |
| **15.3** | **Statistical Reports**  **Reports to DSMB**   * Other Analyses | Copy of the reports to the DSMB Committee |  |  |  |  |  |
| Copy of any Interim Analysis Statistical Reports |  |  |  |  |  |
| Copy of any Other Protocol-Defined Analysis |  |  |  |  |  |
| **15.4** | **Related Correspondence** | Copies of all significant correspondence relating to statistics or the statistical plan for the study |  |  |  |  |  |
| **16.0** | **CENTRALISED LABORATORY** | | | | | | |
| **16.1** | **Research Sample Lab Manual**   * If applicable | Copy of the Research Sample Lab Manual |  |  |  |  |  |
| Copy of the Research Sample Lab Manual Approval and Sign-Off Form   * Signed by Trial Coordinator, Research Sample Representative/PI, Sponsor-Investigator/CPI |  |  |  |  |  |
| Copy of the Biospecimen Collection Forms Template   * Generic Master version |  |  |  |  |  |
| Copy of the Biospecimen Sample Labels, if applicable   * Generic Master version |  |  |  |  |  |
| Copies of other Research Sample Related Manuals |  |  |  |  |  |
| **16.2** | **Centralised Lab Certification**   * If applicable | Copy of the Central Lab Accreditation (i.e. NATA Accreditation Certificate) |  |  |  |  |  |
| **16.3** | **Centralised Lab Reference Ranges**   * If applicable | Copy of the Central Lab Reference Ranges |  |  |  |  |  |
| **16.4** | **Biospecimen Log**   * If applicable | Biospecimen Collection Log Template   * Generic Master version |  |  |  |  |  |
| **16.5** | **Biospecimen Shipment Receipt Tracking** | Copies of courier shipping documents, invoices, receipts, custom declarations, consignment notes, import permits etc. |  |  |  |  |  |
| **16.6** | **Biospecimen Storage Monitoring Documentation**  - If applicable | Copies of any documentation relating to the monitoring of biospecimen storage at the Central Research Laboratory |  |  |  |  |  |
| Copy of the Biospecimen Reconciliation Process |  |  |  |  |  |
| **16.7** | **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** | **LEGAL DOCUMENTATION** | | | | | | |
| **17.1** | **Master Clinical Trial Research Agreement (CTRA)** | Copy of the Master Clinical Trial Research Agreement (CTRA) |  |  |  |  |  |
| **17.2** | **Other Agreements as applicable: e.g. –**   * Material Transfer Agreement (MTA) * Confidentiality Agreement (CDA) * Pharma Agreements * Data Sharing Agreements | Master copies of other Agreements as applicable to the trial |  |  |  |  |  |
| **17.3** | **Correspondence with MCRI Legal** | Copies of all significant correspondence to and from the MCRI Legal Team or relating to any Agreements pertaining to the study. |  |  |  |  |  |
| **18.0** | **FINANCE DOCUMENTATION** | | | | | | |
| **18.1** | **Budget Tracking – Forecasts and Actuals** | A copy of the trial budget, forecast and actuals |  |  |  |  |  |
| **18.2** | **Invoices/Receipts** | Copies of relevant invoices and receipts pertaining to the study, including per patient payments |  |  |  |  |  |
| **18.3** | **Related Correspondence** | Copies of all significant correspondence regarding the study budget, invoice tracking, per patient payments, etc. |  |  |  |  |  |
| **19.0** | **OTHER COMMUNICATION** | | | | | | |
| **19.1** | **Newsletters to Sites** | Copies of Newsletters sent to participating sites |  |  |  |  |  |
| **19.2** | **Other General Correspondence** | Copies of all other significant general correspondence |  |  |  |  |  |
| **20.0** | **PUBLICATIONS/ABSTRACTS** | | | | | | |
| **20.1** | **Publications** | Copies of accepted publications arising from the study |  |  |  |  |  |
| **20.2** | **Abstracts** | Copies of any accepted abstracts arising from the study |  |  |  |  |  |
| **21.0** | **CLINICAL STUDY REPORT** | | | | | | |
| **21.1** | **Clinical Study Report**   * If applicable | Copy of the Final Clinical Study Report |  |  |  |  |  |
| **21.2** | **Statistical Report** | Copy of the Statistical Report |  |  |  |  |  |
| Copy of the Final Statistical Presentation   * if applicable |  |  |  |  |  |
| **22.0** | **STUDY REGISTER – REGISTRATION AND RESULTS POSTING** | | | | | | |
| **22.1** | **Initial Registration with a Trial Registry**   * Copy of Protocol Registration Receipt | Copy of the registration release/receipt of the entry from the Registry |  |  |  |  |  |
| **22.2** | **Updates to Trial Registry:**   * Annual updates * Updates following change in recruitment status * Posting results | Copy of any update to the registration record (annual and changes to recruitment status, protocol elements) |  |  |  |  |  |
| Copy of results posted to the registration record (if applicable) |  |  |  |  |  |
| **22.3** | **Related Correspondence** | Copies of all significant correspondence regarding trial registration |  |  |  |  |  |
| **23.0** | **ARCHIVING** | | | | | | |
| **23.1** | **Archiving Details** | Copy of the Investigator Agreement to Archive Template   * Generic Master version |  |  |  |  |  |
| **23.2** | **Related Correspondence** | Copies of all significant correspondence regarding trial archiving |  |  |  |  |  |
| **FOR DRUG & DEVICE TRIALS ONLY** | | | | | | | |
| **24.0** | **REFERENCE SAFETY INFORMATION (RSI) FOR EACH INVESTIGATIONAL PRODUCT**  *For IMPs this may be the Investigator’s Brochure or approved Product Information. For IMDs this may be a risk analysis report, Investigator’s Brochure, Instructions for Use or Clinical Investigation Plan or protocol* | | | | | | |
| **24.1** | **Current Reference Safety Information**  e.g. Current IB or PI | Full copy of the Investigator Brochure (IB) or the Product Information (PI) |  |  |  |  |  |
| Copies of any Associated Documents (e.g. IB Addendums etc.) |  |  |  |  |  |
| **24.2** | **IB Version Tracker** | Copy of the IB Version Tracker |  |  |  |  |  |
| **24.3** | **IB Signature Pages**   * if applicable | Copy of the IB Signature Pages   * Signed by Sponsor-Investigator, if applicable |  |  |  |  |  |
| **25.0** | **INVESTIGATIONAL PRODUCT** | | | | | | |
| **25.1** | **Product Manufacturing Records:**  if using an unregistered (new) IP:   * Related Correspondence with IP Manufacturer/Importer * Certificates of Analysis (CoA) * Quality Control Release | Copies of any correspondence with Drug Company relating to IP manufacturing or importation   * If applicable |  |  |  |  |  |
| Copies of IP Quality Control Release Documentation relating to the batch of IP supplied for the trial   * If applicable |  |  |  |  |  |
| **25.2** | **IP Ordering Information / Drug Order Form** | Copies of the Instructions/Process for ordering IP (i.e., via IWRS, if applicable) |  |  |  |  |  |
| Copy of the Drug Order Form used by participating sites to order IP   * Generic Master version |  |  |  |  |  |
| **25.3** | **IP Packaging and Labelling** | Copy of the Secondary Label |  |  |  |  |  |
| Copy of the Secondary Label Approval Form   * Signed by Sponsor-Investigator, Pharmacy Representative and Sponsor Representative |  |  |  |  |  |
| Copy of the Primary Label   * If applicable |  |  |  |  |  |
| **25.4** | **Instructions for Handling IP and Trial Related Materials**  **Pharmacy Manual** | Copy of the Pharmacy Manual |  |  |  |  |  |
| Copies of any Other IMP Handling Instructions   * If applicable |  |  |  |  |  |
| **25.5** | **Documentation of Central IP Shipment** | Copies of all Import Permits  (e.g., AQIS Import Permit, if applicable) |  |  |  |  |  |
| Copies of all Shipping Records, where applicable |  |  |  |  |  |
| Copies of all Import Letter – study specific   * Signed by Sponsor/ Sponsor-Investigator or Pharmacy delegate |  |  |  |  |  |
| **25.6** | **Documentation of Central IP:**   * Quarantines * Returns * Destructions/Drug Destruction Form | Copy of the Drug Destruction Form Template   * Generic Master version |  |  |  |  |  |
| Copy of the process for the reporting of any IP Deviations (i.e., temperature excursions, IP complaints, IP quarantines) and associated forms at sites |  |  |  |  |  |
| Copy of the process for the Return/Destruction of any unused IP at the end of the study |  |  |  |  |  |
| **25.7** | **Documentation of Central IP Dispensing:**   * Accountability and Reconciliation (used/unused/destroyed) * Drug Accountability Log Templates | Copy of the Bulk Drug Accountability Log Template   * Generic Master version |  |  |  |  |  |
| Individual Drug Accountability Log Template   * Generic Master version |  |  |  |  |  |
| **25.8** | **Copies of Material Safety Data Sheets (MSDS)** | Copy of the Material Safety Data Sheet (MSDS) for each drug/IP used in the study. |  |  |  |  |  |
| **25.9** | **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.**

**Ensure a copy of the completed Review Form is also emailed to the MCRI Sponsorship Committee at:** [**MCTC@mcri.edu.au**](mailto:MCTC@mcri.edu.au)

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

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

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

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