Electronic Trial Master File (eTMF) – Table of Contents Document Filing Guideline

Key Terms:

Placeholders: In Florence, a Placeholder is just what the name states - a spot that holds a place for a future document. When you are developing a study, you usually know from the outset, the certain 'key documents' that you will require in the future. Creating a Placeholder (also defined as a digital "sticky note") upfront, ensures that you hold a place for an expected Document, guaranteeing that you won't overlook them in the future. Some examples include CVs, GCP training certificates, Master PICFs, ethics approval certificates, etc. These can be used to create tasks and generate reports on binder completeness.

eLogs: An eLog is a digital log which has data continuously added to it to list actions taken, approvals, etc. Florence allows the user to create and maintain eLogs directly within the platform itself, avoiding the need to create a template log outside of Florence and subsequently importing the template log into Florence. The user creates log templates for your team so that everyone has a standardised way of recording and storing the data. With eLogs, you can create entries, edit entries, request signatures and sign both entries and the entire log within the Florence platform. Suggested template eLogs are available within the Florence platform for your use.

Section	Contents	Document Filing Guideline / Comments / Available Templates
1.0	**Central Trial Coordination Team**	
1.1	Contact List	**Existing Placeholders:** • **Central Trial Site Contact List** *The Contact List should include all key research team staff, i.e. Sponsor-Investigator/CPI, Country Lead Investigators, Lead Clinical Trial Coordinator, Trial Statistician, Data Manager, IP Supply Vendor, Trial Steering Committee, Data Safety Monitoring Committee, Approving HREC, Medical Monitors, Translational Research Laboratory Personnel etc.*
1.2	Signature and Delegation of Duties Log	**Existing Placeholders:** • **Signature and Delegation of Duties Log -** Include all key research team personnel from the Central Trial Coordinating Team. TEMPLATE Signature Log & Delegation of Duties *If you wish to use the Florence eLog, you will need to delete this placeholder and import the relevant template eLog.*

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		The Signature and Delegation of Duties Log should list all key research team personnel from the Central Trial Coordinating Team involved with the trial – i.e. the Sponsor-Investigator, all Associate-Investigators named in the protocol, Trial Coordinator, Statistician, Database Manager, Members of the Trial Management Group. *Note: Completed Site-Specific Signature & Delegation of Duties Logs must be filed in Section 1.2 of the corresponding Site Investigator File (SIF).*
1.3	CVs	**Existing Placeholders:** • **CV Sponsor Investigator** • **CV Trial Coordinator** • **CV Statistician** • **CV Lead Data Manager** **Documents to be filed in this Section include:** • **Original Curriculum Vitae –** CVs must be signed and dated within the last two years. TEMPLATE Investigator Short CV • **Copies of Medical Licenses, if applicable** *CVs must include details of qualifications, training and previous appointments of all staff involved in the study.* *We recommend you shortcut to a centrally filed copy of each CV to reduce administrative burden.*
1.3.1	Other CVs	**Documents to be filed in this section include:** • **Original Curriculum Vitae** from all other members of the Central Trial Coordinating Team **–** CVs must be signed and dated within the last two years. TEMPLATE Investigator Short CV • **Copies of Medical Licenses, if applicable** *CVs must include details of qualifications, training and previous appointments of all staff involved in the study.* *We recommend you shortcut to a centrally filed copy of each CV to reduce administrative burden.*
1.4	GCP Training Certificates	**Existing Placeholders:** • **GCP Cert. Sponsor Investigator** • **GCP Cert. Trial Coordinator** • **GCP Cert. Statistician** • **GCP Cert. Lead Data Manager** *GCP training must be completed every three years to remain current. We recommend you shortcut to a centrally*

Section	Contents	Document Filing Guideline / Comments / Available Templates
		filed copy of each GCP Certificate to reduce administrative burden. *Related Link:* You can organise GCP training here.
1.4.1	Other GCP Training Certiicates	**Documents to be filed in this section include:** • **GCP training certificates** from all other key research team personnel from the Central Trial Coordinating Team. *GCP Training is required for all staff listed on the Signature & Delegation of Authority Log.* *GCP Training must be completed every three years to remain current. We recommend you shortcut to a centrally filed copy of each GCP Certificate to reduce administrative burden.*
1.5	Other Training Certificates	**Documents to be filed in this section include:** • **Other training certificates from all other key research team personnel from the Central Trial Coordinating Team.**
1.6	Wet Ink Signatures	**Existing Placeholders:** *Only applicable if not using a wet ink signature log* • **Signature Page Sponsor-Investigator** • **Signature Page Trial Coordinator** • **Signature Page Statistician** • **Signature Page Lead Data Manager** **Documents to be filed in this section include:** • **Wet Ink Signature Log** OR • **Wet Ink Signature Pages from all key research team personnel from the Central Trial Coordinating Team who digitally sign documents using Florence** *The wet ink signature log is a paper-based form which must be scanned, certified, and uploaded to Florence at the end of the trial. An original paper copy of wet ink signatures must be kept by the site.* *We recommend Melbourne Children's Campus staff shortcut to a centrally filed copy of their wet ink signature page to reduce administrative burden.*
1.6.1	Other Wet Ink Signatures - *Only applicable if not using a wet ink signature log*	**Documents to be filed in this section include:** • **Wet Ink Signature Pages from all other key research team personnel from the Central Trial Coordinating Team.**

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2.0	**Project Management**	
2.1	Trial Start-Up Checklist	**Existing Placeholders:** • **Trial Start-Up Checklist** TEMPLATE Trial start-up checklist
2.2	Site Selection Documentation	**Documents to be filed in this Section include:** • **CRO/Vendor Selection Criteria Form –** completed and signed. • **Drug Distribution and Storage Facility Questionnaire** – completed with details of any follow-up actions clearly documented. • **Pre-Trial Site Visit Agenda** • **Pre-Trial Site Visit Checklist –** completed to reflect visit • **Pre-Trial Site Selection Visit Report** – completed and reviewed • **Site Feasibility Questionnaire Template** TEMPLATE Feasibility questionnaire • **Site Feasibility Questionnaire –** completed • **Site Feasibility Assessments** - completed • **Clinical CRO/ Vendor Assessment Form** – completed • **Vendor Assessment Form** – completed with details of any follow-up actions clearly documented • **CRO Vendor Assessment Report** – completed post assessment • **Vendor Acceptance/Rejection Letter** • **Study Vendor Log –** maintained by Trial Coordinator throughout study • **Any significant correspondence relating to Site Feasibility and Site Selection** • **Site Feasibility Tracker**
2.3	Administration	**Documents to be filed in this Section include:** • **Roles and Responsibilities Matrix** • **Any significant correspondence**
2.4	Trial Meeting Agenda/Minutes, Notes, etc.	**Documents to be filed in this Section include:** • **Trial meeting agenda's and minutes** of every meeting with the Sponsor-Investigator and/or research team i.e. internal team meetings
2.5	Significant Team Correspondence & Communication including Emails, etc.	**Documents to be filed in this Section include:** • All other significant correspondence
3.0	**Protocol/Protocol Amendments**	

Section	Contents	Document Filing Guideline / Comments / Available Templates
3.1	Protocol Version Tracker	**Existing Placeholder:** • **Protocol Version Tracker** *If you wish to use the Florence eLog as your version tracker you will need to delete this placeholder and import the relevant template eLog.*
3.2	Current HREC Approved Study Protocol and Signed Protocol Signature Page / Investigator Agreement Page	**Existing Placeholders:** • **Study Protocol –** current HREC approved and signed Final Protocol • **Signed Protocol Signature Pages –** signed by Sponsor-Investigator or Sponsor Representative only. **Other Documents to be filed in this Section:** • **Previous protocol versions Signed Protocol Signature Pages** *Note: If study is sponsored by MCRI, protocol should be based on MCRI Protocol Template.* *Protocol signature pages which are also signed by participating Site Investigators are filed in Section 3.2 and 3.3 of the corresponding Site Investigator File (SIF).*
3.3	Protocol – Evidence of review and approval by Sponsor	**Documents to be filed in this Section include:** • **Protocol Review Checklist – Study Coordinator** • **Protocol Review Checklist – Statistician** • **Protocol Approval and Sign-Off Form** – signed by Trial Coordinator, Statistician and Sponsor Investigator prior to HREC submission. *Note: It is expected that with each protocol amendment a review checklist and protocol approval and sign-off form is completed, signed and filed.*
3.4	Peer Review – Evidence of Review	**Documents to be filed in this Section include:** • **Evidence of Peer Review** *Related Links:* RCH Template *Note: this may not be applicable if the trial underwent MCRI Sponsorship approval process.*
3.5	Non-Compliance Reports and Central Non-Compliance Log	**Existing Placeholders:** • **Master Non-Compliance Report Form** • **Master Non-Compliance Review Form** • **Central Non-Compliance Log**

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		Note: Non-compliance report forms completed by Sites are filed in section 3.5 of the corresponding Site Investigator File (SIF). *If you wish to use the Florence eLog as your non-compliance log you will need to delete this placeholder and import the relevant template eLog.*
3.6	Sponsor-level Serious Breaches and CAPAs	**Existing Placeholders:** • **Master Corrective and Preventive Action Plan** • **CAPA Tracking Log** *If you wish to use the Florence eLog as CAPA tracking log you will need to delete this placeholder and import the relevant template eLog.* *Related Links:* SOP - Corrective And Preventative Action (CAPA) Plan **Documents to be filed in this Section include:** • **Sponsor-level Corrective and Preventive Action Plans (CAPA) –** to be completed and signed by Sponsor-Investigator and submitted to the MCRI Sponsorship Committee for review, detailing any corrective and preventative action to be taken in addressing the serious breach encounted at sponsor level. • **Sponsor-level Corrective and Preventive Action Plan (CAPA) Reviews –** completed and assessed by the MCRI Sponsorship Committee detailing any corrective and preventative action to be taken in addressing serious breaches encountered at sponsor-level.
3.7	Copy of all Serious Breach reports to Sponsor-Investigator/HREC or Regulatory Authorities, if applicable	**Documents to be filed in this Section include:** • **Copies of all Serious Breach Reports submitted to Ethics, including supporting ERM documentation and any return acknowledgment** • **Copies of all Serious Breach Reports submitted to Regulatory Authorities any return acknowledgment** *Related Links:* NHMRC guidance Reporting of Serious Breaches of Good Clinical Practice (GCP)

Section	Contents	Document Filing Guideline / Comments / Available Templates
3.8	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to protocol development, protocol amendments, sponsor-level serious breaches and CAPAs** *Note: Site-level correspondence related to serious breaches and CAPAs is filed in section 3.6 of the corresponding Site Investigator File (SIF).*
4.0	**Participant Information & Consent Forms** (Generic / Master templates)	
4.1	PGICF & PICF Version Tracker	**Documents to be filed in this Section include:** • **PGICF & PICF Version Tracker(s) -** to be completed and maintained by Trial Coordinator to track the history of the Master PICFs and subsequent amendments. Ensure the tracker document is appropriately labelled with the correct version numbers and approval dates. Consider country-specific master version trackers if your trial operates in global areas. *A template Florence PICF / PGICF Version tracker eLog is available to import to this section.*
4.2	Master PGICF & PICF – Current HREC Approved Version(s)	**Documents to be filed in this Section include:** • **Template Master PGICF & PICF** RCH PGICF & PICF Guidelines and Templates *Note: For multi-centre studies, file the Master PGICF & PICF here. Site-specific PGICF & PICF documents to be filed in the Site Information File (SIF).*
4.3	Other Participant Information	**Documents to be filed in this Section include:** • **Copies of other approved Participant Information**
4.4	PGICF & PICF – Evidence of Review and Approval	**Documents to be filed in this Section include:** • **PGICF / PICF Review Checklist – Study Coordinator** • **PGICF / PICF Approval and Sign-Off Form** – signed by Trial Coordinator and Sponsor Investigator prior to HREC submission. *Note: It is expected that with each protocol amendment a review checklist and protocol approval and sign-off form is completed, signed and filed.*
5.0	**Regulatory Documents**	
5.1	Site Green Light Approval form(s)	**Existing Placeholder** • **Master Site Green Light Approval Form**

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		*Note: This is a **mandatory** requirement for all participating sites and must be completed prior to officially activating a site to recruitment/randomisation. Prior to authorising the start of a clinical trial and the initiation of research sites, the sponsor must ensure that all approvals, contracts and necessary documentation are in place. Records must be available to verify that all necessary essential documents have been received by the sponsor prior to the authorisation to start the clinical trial at each site. This should include confirmation that they have been reviewed by an appropriately delegated representative of the sponsor. Once this check is complete, trial activities at site can commence. This process is referred to as the **'regulatory green light'.*** *Note: In the Comments column of the TMF Table of Contents, indicate that site-specific Green Light Approval Forms are filed in section 5.3of the corresponding Site Investigator File (SIF).*
5.2	TGA Acknowledgement Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX)	**Documents to be filed in this Section include:** • **Copy of the CTN Acknowledgement listing all participating sites** • **Copy of the CTX Acknowledgement listing all participating sites**
5.3	CTN/CTX Submission(s)	**Documents to be filed in this Section include:** • **Copy of the electronic CTN Submission to the TGA listing participating sites** • **Copy of the eBS Submission Document from the TGA, if available** • **Copy of the TGA CTN Invoice, if available** • **Proof of CTN Payment, if available**
5.4	Other TGA Correspondence	**Documents to be filed in this Section include:** **All significant correspondence to and from the TGA**
5.5	International Regulatory Submissions (e.g. MHRA, HPRA, FDA, etc)	**Documents to be filed in this Section include:** • **Relevant International Regulatory Submissions (e.g. IND applications), if available**
5.6	International Regulatory Approvals	**Documents to be filed in this Section include:** • **Copies of International Regulatory Certificates of Approvals**
5.7	International Regulatory Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence to and from any Regulatory Agency**
5.8	Supplementary FDA Documents	**Documents to be filed in this Section include:** • **Financial Disclosure Form (FDA 3454 Form), if applicable**

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		• **Statement of Investigator Form (FDA 1572 Form), if applicable** *Note: FDA Forms 3454 and 1572 only need to be completed by the Principal Investigator at each participating site.* *Note: FDA Form 1572 only needs to be completed for studies which fall under an IND in the USA. Always obtain the most recent version of the form directly from the FDA website; available online.* *The FDA also produce a Set of Instructions to assist Investigators with completion of the 1572 form as well as a FAQ.* *Note: Form 3454 needs to be completed for all studies which have sites bases within the USA, regardless of whether the study falls under an IND or not; i.e.* ***Is clinical investigator financial disclosure information required in IND or IDE applications?*** ***A:** No, IND/IDE Sponsors are not required to submit information regarding clinical investigator financial interests or arrangements in IND or IDE applications. They are, however, required to collect this information before a clinical investigator participates in a clinical study and clinical investigators are required to disclose financial information to Sponsors.* *Always obtain the most recent version of the form directly from the FDA website; available online.* *The FDA also produce a Guidance Document to assist Sponsors with Financial Disclosure forms.* *Note: In the Comments column of the TMF Table of Contents, indicate that completed site-specific 1572 and 3454 forms are filed in section 5.2 of the corresponding participating Site Investigator File (SIF).*
6.0	**Sponsorship**	
6.1	Sponsor Authorisation Letter	**Existing Placeholder(s):** • **A copy of the MCRI Certificate of Sponsorship** **Other documents to be filed in this section include:** • **Subsequent copies of MCRI Certificates of Sponsorship**

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		File all Certificates as a new document – do not file as version updates.
6.2	Completed Risk Assessment and Risk Management Tool	**Existing Placeholder(s):** • **Completed MCRI Sponsorship Application including completed Risk Management Table** **Other Documents to be filed in this Section include:** • **Copies of any subsequent submissions to the MCRI Sponsorship Committee** i.e. in relation to protocol amendments. *Related Links:* - SOP in applying for a Certificate of Sponsorship - Application form and Risk Assessment Matrix
6.3	Related Correspondence and Meeting Minutes	**Documents to be filed in this Section include:** • **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	**Existing Placeholder(s)** • **Initial Ethics Committee Approval Letter** **Other Documents to be filed in this Section include:** • **Letters/Acknowledgement relating to the original Protocol/PICF/IB etc** • **Subsequent Amendment approvals/acknowledgement from the Ethics Committee** • **Ethics Aproval Letters/Acknowledgements relating to ALL other project submissions.** *Note: Only **LEAD HREC** approval letters/acknowledgements need to be filed here. For local country specific approvals, in the Comments column of the TMF Table of Contents, indicate that these documents are filed in section 6.2 of the corresponding Site Investigator Files (SIF).*
7.2	Ethics Submission Documentation Initial & Amendments Including responses to HREC queries	**Existing Placeholder(s)** • **Complete Initial Ethics application relating to the original Protocol/PICF/IB etc, including a copy of the HREA** **Other Documents to be filed in this Section include:** • **A copy of the Responses to HREC Queries, if applicable**

Section	Contents	Document Filing Guideline / Comments / Available Templates
		• **Complete copy of any Protocol Amendments submitted to Ethics, including supporting ERM documentation** • **Copies of all additional Amendments or Project Notifications submitted to Ethics, including supporting ERM documentation.** *Note: Download submissions from the submissions tab in ERM. This will generate a PDF of the completed HREA form and list of submitted documents. The document will have a date generated field (in the footer), indicating the date of submission.* *Related Links:* *Ethics submission resources and information*
7.3	Ethics Committee Composition, Constitution & Statement of Compliance	**Existing Placeholder(s)** • **Ethics Committee Composition** **Other Documents to be filed in this Section include:** • **Statement of Compliance of Leading EC** *Note: If Ethics Committee Composition is not provided by the Lead HREC, then evidence documenting this decision must be filed in this section of the TMF relevant to this communication.*
7.4	Annual Project Progress Reports and Final Project Report	**Documents to be filed in this Section include:** • **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.** *Note: Annual Safety Reports to HREC are to be filed in Section 11.4.*
7.5	Related Correspondence	**Documents to be filed in this Section include:** • **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	**Existing Placeholder(s)** • **Manual of Procedures (MoP)Document** **Documents to be filed in this Section include:**

Section	Contents	Document Filing Guideline / Comments / Available Templates
		• **Any Manual of Procedures associated documents**, if applicable • **Study-Specific SOPs** • **Imaging Manual** • **Imaging Charter** • **Central Review Manual** • **Nuclear Medicine Manual** • **Ophthalmology Manual** • **Radiotherapy Manual** • **Any Study Specific SOP associated documents, if applicable** *Related Links:* SOP creation, implementation and revision guideline
9.0	**Site Training**	
9.1	SIV Presentation	**Documents to be filed in this Section include:** • **Site Initiation Visit Presentation slide set** – generic master version of site initation presentation • **Site Initiation Agenda** – generic master version • **Site Initiation Booking Letter** - generic master version • **Essential Document Request Letter** – generic master version • **Site Initiation Attendance Log** – generic master version • **Site Initiation Follow Up Letter**– generic master version • **Site Activation Letter** – generic master version *Related Links:* SOP on monitoring visit activities Section: Site Initiation Visit (SIV) training presentation. *Note: In the Comments column of the TMF Table of Contents, indicate that Site-Specific versions of the SIV presentation, agenda and attendance log are filed in the in section 9.1 of the corresponding Site Investigator File (SIF).*
9.2	Investigator Meeting	**Documents to be filed in this Section include:** • **Investigator Meeting Presentation slide set** • **Investigator Meeting Attendance Log** – completed and signed by all attendees *Note: If applicable, file all relevant documents e.g. logistics of meetings, all relevant correspondence etc.*
9.3	Other Presentations	**Documents to be filed in this Section include:** • **File presentations other than the generic Master Site Initiation Visit presentation used for site**

Section	Contents	Document Filing Guideline / Comments / Available Templates
		training purposes here. For example, presentations used for site re-training, training presentations on the study database etc.
9.4	Training Logs	**Documents to be filed in this Section include:** • **Study-Specific Training Log -** generic master version • **Other Training Attestation Forms, if applicable -** generic master version *A template Florence Training eLog is available to import to this section.* *Related Links:* TEMPLATE Training Log *Note: In the Comments column of the TMF Table of Contents, indicate that completed versions of the Site-Specific versions of the Training Logs/Forms are filed in the in section 1.5 of the corresponding Site Investigator File (SIF).*
9.5	Other training resources	**Documents to be filed in this Section include:** • **Copies of other site-specific training resources/ materials provided to sites.**
10.0	**Participant Recruitment**	
10.1	Pre-Screening Log Template	**Documents to be filed in this Section include:** • **Pre-Screening Log -** generic master template TEMPLATE – Pre-screening log *A template Florence Pre-screening eLog is available to import to this section. If you wish to use the Florence eLog, you will need to delete this placeholder and import the relevant template eLog* *Related Links:* Recruitment Guideline
10.2	Consent, Screening & Enrolment Log Template	**Documents to be filed in this Section include:** • **Consent, Screening & Enrolment Log -** generic master template TEMPLATE- consent, screening & enrolment log *A template Florence Consent, Screening and Enrolment eLog is available to import to this section. If you wish to use the Florence eLog, you will need to delete this placeholder and import the relevant template eLog.*
10.3	Participant ID Log Template	**Documents to be filed in this Section include:** • **Participant ID Log -** generic master template

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		A template Florence Participant ID eLog is available to import to this section. If you wish to use the Florence eLog, you will need to delete this placeholder and import the relevant template eLog.
11.0	**Participant Randomisation and Registration Procedures**	
11.1	Randomisation Manual or Participant Registration Procedure	**Documents to be filed in this Section include:** • **Randomisation Manual** • **Participant Registration Procedure**
11.2	Records of Unblinding (all participants)	**Documents to be filed in this Section include:** • **All records of Unblinding during study conduct and reasons for unblinding**
11.3	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to participant randomisation and unblinding procedures.**
12.0	**Data Management – Forms & Procedures**	
12.1	Blank Sample CRF	**Documents to be filed in this Section include:** • **For eCRFs; annotated* CRFs** • **For Paper CRFs; blank CRFs** *Related Links:* SOP for CRF creation, including a sample document. *Note: Completed paper CRFs are considered part of the TMF and must be filed separately from the TMF.* **Annotated Case Report Form Definition:* *An annotated case report form (CRF) is a blank CRF with annotations that document the location of the data with the corresponding names of the datasets and the names of those variables included in the submitted datasets. The annotated CRF is a blank CRF that includes forms and maps each item on the CRF to the corresponding variables in the database. The annotated CRF should provide the variable names and coding for each CRF item included in the data tabulation datasets. All of the pages and each item in the CRF should be included. The annotated CRF should be provided as a PDF file. Name the file blankcrf.pdf.*
12.2	CRF Completion Guidelines	**Documents to be filed in this Section include:** • **CRF Completion Guidelines**
12.3	Trial-Specific Data Management Plan	**Existing Placeholders** • **Data Management Plan** • **Data Sharing Plan** • **Source Document Plan** - generic master

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		Other Documents to be filed in this Section include: • **Data Validation Plan** • **Medical Review Plan and associated Review Forms -** File template review forms here. Complete review forms are filed separately. • **Other Data Review Committees and/or Plans.** *Related Links:* Data Management Plan Template Source Document Plan Guidance and Template *Note: In the Comments column of the TMF Table of Contents, indicate that completed Source Document Plans are filed in section 13.2 of the corresponding Site Investigator File (SIF).*
12.4	Database Management Documentation - DB Specification - DB Testing - Database Version Tracker	**Documents to be filed in this Section include:** • **Database Specifications** • **Database Review and Testing Log** • **Database Version Tracking Log** – to be completed by the Database Manager (if applicable) or Trial Coordinator to track the history of the database and any subsequent amendments to the database. Ensure the tracker document is appropriately labelled and the footer contains study acronym/name. • **Transfer of Data Forms** *Related Links:* MCRI provides technical support and advice for REDCap. Please contact CEBU for instructions on Database management.
12.5	Trial Database Design Approval Form	**Documents to be filed in this Section include:** • **Database Approval Form** – to be completed by the Database Manager (if applicable) or Trial Coordinator at the time of database release from demo mode into production mode. Form signed by Database Manager (if applicable), Trial Coordinator, Statistician and Sponsor-Investigator. *Note: It is expected that with each database amendment a Database Approval Form is completed, signed and filed.*
12.6	Electronic Data Capture (EDC) System Application Form - Template	**Documents to be filed in this Section include:** • **Electronic Data Capture (EDC) System Account Application Form** – generic master template
12.7	Completed Electronic Data Capture (EDC) SystemApplication Forms	**Documents to be filed in this Section include:** • **Electronic Data Capture (EDC) System Account Application Form** – completed and signed forms

Section	Contents	Document Filing Guideline / Comments / Available Templates
		from key research personnel requiring database access from the Central Trial Coordinating Team. *Note: Completed site-level EDC Acount Application Forms must be filed in Section 13.1 of the corresponding Site Investigator File (SIF).*
12.8	Related Correspondence	**Documents to be filed in this Section include:** • **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	**Existing Placeholder(s)** • **Expedited Safety (SAE) Report Form Template** • **Safety Event (SAE) Review Form Template** TEMPLATE - Expedited Safety Report form **Other Documents to be filed in this Section include:** • **Safety Monitoring Plan** • **Safety Reporting Guidelines for Sites Example** • **Expedited Safety (SAE) Report Coversheet Template** • **Expedited Safety (SAE) Report Completion Instructions** • **Expedited Pregnancy Coversheet** *(for drug trials, if applicable)* • **Expedited Pregnancy Report Form** – *(for drug trials, if applicable)* • **Expedited Pregnancy Report Completion Instructions** – *(for drug trials, if applicable)* • **Instructions for Medical Monitors** • **SAE Form for Non-MCRI-Sponsored Studies** – this would be filed when MCRI is the Coordinating Lead site for a collaborative group trial and has been delegated task of managing the TMF. • **Review of Safety Events: Instructions for Trial Coordinator** *Related Links:* SOP - Safety monitoring & reporting for products with IMDs/IMPs *Note:* For all documents ensure that headers and footers are labelled appropriately and contain the study acronym or short title name, version number and date.

Section	Contents	Document Filing Guideline / Comments / Available Templates
13.2	Copy of Completed Expedited Safety Report Forms (all SAEs, suspected SUSARs and USMs) and associated correspondence from all Sites	**Documents to be filed in this Section include:** • **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 *Note: In the Comments section of the TMF Table of Contents note that all submitted Expedited Safety Report forms received from Sites and their corresponding Safety Event Review form received from Medical Monitors will be filed in a separate SAE Folder throughout study conduct and all filed in Section 13.2 of TMF at the end of the study.*
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.	**Documents to be filed in this Section include:** • **Copies of Annual Safety Reports submitted to Ethics, including supporting ERM documentation** • **Copies of SUSARs/URSAEs, SSIs and USMs submitted to Ethics, 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** • **Evidence of notification of all trial SUSARs/URSAEs, SSIs and USMs to participating sites** • **6-monthly SUSAR Line-Listing received from Drug Companies, including evidence they have been actioned accordingly.** *Related Links:* - RCH Reporting Guidelines - Sponsor-Investigator Safety Reporting Flow Chart (IIT) - Site PI Safety Reporting Flow Chart (IIT)
13.4	Copy of all Serious Breach reports to Sponsor-Investigator/HREC or Regulatory Authorities, if applicable	**Documents to be filed in this Section include:** • **Copies of all Serious Breach Reports submitted to Ethics, including supporting ERM documentation and any return acknowledgment** • **Copies of all Serious Breach Reports submitted to Regulatory Authorities any return acknowledgment** *Related Links:* NHMRC guidance Reporting of Serious Breaches of Good Clinical Practice (GCP)

Section	Contents	Document Filing Guideline / Comments / Available Templates
13.5	Written Procedure for Unblinding in either: • The case of a medical emergency • For safety reporting purposes	**Documents to be filed in this Section include:** • **Emergency Procedures for Unblinding Manual**
13.6	Other related correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to safety monitoring and reporting requirements.** *Note: DSMB related correspondence is filed in Section 13.6.4 of the TMF.*
14.0	**Study Quality Assurance, Monitoring, Audits & Inspections**	
14.1	Clinical Monitoring Plan	**Existing Placeholder(s)** - **Clinical Monitoring Plan** TEMPLATE - Clinical Monitoring Plan **Other Documents to be filed in this Section include:** • **Risk Assessment and Risk Management Tool for Clinical Trials** Risk Assessment & Risk Management Template • **An other monitoring associated documents** *Related Links:* *SOP Safety Monitoring and Reporting Procedure for MCRI-sponsored investigator-Initiated Trials of Medicines/Medical Devices*
14.2	Clinical Monitoring Plan – Evidence of Review and Approval by Sponsor-Investigator	**Documents to be filed in this Section include:** • **Clinical Monitoring Plan Approval and Sign-Off Form** – signed by Sponsor Investigator. *Note: It is expected that with each Clinical Monitoring Plan revision and up-version, an approval and sign-off form is completed, signed and filed.*
14.3	Monitoring Log	**Existing Placeholder(s)** • **Site Monitoring and Visit Log** – Record all site visits completed, whether Site Monitoring or Site Audit visits are performed, on this Log. *If you wish to use the Florence eLog, you will need to delete this placeholder and import the relevant template eLog.*
14.4	Monitoring Visit Reports, including Evidence of Review and Approval by Sponsor/Delegate	**Documents to be filed in this Section include:** • **SIV Report** (template) • **Site Monitoring Visit Report Template** Site Monitoring Vist Report Template

Section	Contents	Document Filing Guideline / Comments / Available Templates
		Note: In the Comments column of the TMF Table of Contents, indicate that completed Site-Specific Monitoring Visit Reports are filed in section 14.3 of the corresponding Site Investigator File (SIF).
14.5	Related Monitoring Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to site monitoring.**
14.6	**Data Safety Monitoring Board (DSMB)**	
14.6.1	DSMB Charter	**Documents to be filed in this Section include:** • **DSMB Charter –** The members of the DSMC must sign the charter to indicate their approval of the content and agreement to adhere to the terms of the charter. TEMPLATE – DSMB Charter *Related Links:* GUIDANCE – Data Safety Monitoring Board
14.6.2	Charter – Evidence of Review and Approval by Sponsor-Investigator	**Documents to be filed in this Section include:** • **DSMB Charter Approval and Sign-Off Form** – signed by Trial Coordinator, Statistician, Sponsor Investigator and Sponsor Representative. Furthermore, the members of the DSMC must sign the Charter to indicate their approval of the content and agreement to adhere to the terms of the charter. *Note: It is expected that with each DSMB Charter revision and up-version, an approval and sign-off form is completed, signed and filed in the TMF.*
14.6.3	DSMB Meeting Minutes	**Documents to be filed in this Section include:** • **All minutes from DSMB meetings held throughout trial conduct** *Note: The DSMB may have minutes taken for both the Open and Closed meetings. Meeting minutes should be reviewed, approved and signed by the DSMB Chair and distributed as soon as possible after the DSMB meeting. The person taking minutes for the closed meeting will be independent of the trial team and must ensure that the minutes of the closed meeting remain confidential until the completion of the study. Minutes from the closed DSMB meeting are not filed in the TMF until the end of the study.*
14.6.4	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence to and from the DSMB**

Section	Contents	Document Filing Guideline / Comments / Available Templates
		• **All other DSMB related correspondence.**
14.7	**Trial Steering Committee (TSC)/Trial Management Committee (TMC)/Other Committees**	
14.7.1	Steering Committee Charter(s)	**Documents to be filed in this Section include:** • **Trial Steering Committee Charter** TSC Charter Template
14.7.2	Documentation/Approval by Sponsor-Investigator	**Documents to be filed in this Section include:** • **Charter Approval and Sign-Off Form** – signed by Trial Coordinator, Statistician, Sponsor Investigator and Sponsor Representative. *Note: It is expected that with each Charter revision an approval and sign-off form is completed, signed and filed in the TMF.*
14.7.3	Committee Meeting Minutes	**Documents to be filed in this Section include:** • **All minutes from Trial Steering Committee/Other Trial Committee meetings held throughout trial conduct** *Note: Meeting minutes should be reviewed, approved and signed by the Committee Chair and distributed as soon as possible after the scheduled meeting.*
14.8	Local Research Governance Office Documentation – all sites: - Copy of all Audit Reports	**Documents to be filed in this Section include:** • **Copies of all Audit Reports sent to Local Research Governance Offices** *Note: RGO Acknowledgements of submitted Audit reports should be filed in Section 6.5 of the corresponding Site Investigator File (SIF).*
14.9	Regulatory Inspections: - Reports - Related Correspondence	**Documents to be filed in this Section include:** • **Copies of all Regulatory Inspection Reports** • **Any correspondence related to Regulatory Inspections**
15.0	**Statistics**	
15.1	Statistical Analysis Plan (SAP)	**Existing Placeholder(s)** • **Statistical Analysis Plan (SAP)** *Related Links:* Book an appointment with CEBU to arrange a consultation to discuss your Statistical Analysis Plan (SAP).
15.2	Statistical Analysis Plan – Evidence of review and approval from Sponsor-Investigator	**Documents to be filed in this Section include:** • **Statistical Analysis Plan (SAP) Approval and Sign-Off Form** – signed by Statistician and Sponsor Investigator.

Section	Contents	Document Filing Guideline / Comments / Available Templates
		Note: It is expected that with each SAP revision and up-version, an approval and sign-off form is completed, signed and filed in the TMF.
15.3	Statistical Reports - Reports to DSMB - Other Analyses	**Documents to be filed in this Section include:** • **Copy of the reports to DSMB Committee** TEMPLATE – DSMB Open Report Template • **Copy of any Interim Analyis Statistical Reports** • **Copy of any Other Protocol-Defined Analysis** *Note: The DSMB may have reports generated for both the Open and Closed meetings, depending on you're the requirements outlined in your Charter. Reports generated for the the closed DSMB meeting are generally confidential and not filed in the TMF until the end of the study.*
15.4	Related Correspondence	**Documents to be filed in this Section include:** • **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	**Documents to be filed in this Section include:** • **Research Sample Lab Manual** • **Research Sample Lab Manual Approval and Sign-Off Form** – signed by Trial Coordinator, Research Sample Representative/PI, Sponsor-Investigator • **Biospecimen Collection Forms Template** • **Biospecimen Sample Labels** - if applicable • **Other Research Sample Related Manuals**
16.2	Centralised Lab Certification - If applicable	**Documents to be filed in this Section include:** • **Copy of the Central Lab Accreditation** – i.e. NATA Accreditation Certificate, only if a Central Lab is completing the analysis on behalf of all sites. *Note: In the Comments column of the TMF Table of Contents, indicate that Laboratory Accreditation for Local Laboratories are filed in section 16.2 of the corresponding Site Investigator File (SIF).*
16.3	Centralised Lab Reference Ranges - If applicable	**Documents to be filed in this Section include:** • **Copy of the Central Lab Reference Ranges** – only if a Central Lab is completing the analysis on behalf of all sites. *Note: In the Comments column of the TMF Table of Contents, indicate that Local Lab Reference Ranges for*

Section	Contents	Document Filing Guideline / Comments / Available Templates
		participating sites are filed in section 16.3 of the corresponding Site Investigator File (SIF).
16.4	Biospecimen Log - If applicable	**Documents to be filed in this Section include:** • **Biospecimen Collection Log Template** *Note: In the Comments column of the TMF Table of Contents, indicate that site-specific Biospecimen Collection Logs are filed in section 16.4 of the corresponding Site Investigator File (SIF).*
16.5	Biospecimen Shipment Receipt Tracking	**Documents to be filed in this Section include:** • **Copies of courier shipping documents, invoices, receipts, custom declarations, consignment notes, import permits etc.**
16.6	Biospecimen Storage Monitoring Documentation - If applicable	**Documents to be filed in this Section include:** • **Any documentation relating to the monitoring of biospecimen storage at the Central Research Laboratory** • **Biospecimen Reconcilation Process**
16.7	Related Correspondence	**Documents to be filed in this Section include:** • **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)	**Existing Placeholders:** • **Master Clinical Trial Research Agreement (CTRA)** *Related Links: Governance and Regulatory Documents* *Related Links: Book an appointment with the Legal Team to arrange a consultation to discuss your Clinical Trial Research Agreement.*
17.2	Other Agreements as applicable: e.g. Material Transfer Agreement (MTA), Confidentiality Agreement (CDA), Pharma Agreements, Data Sharing Agreements	**Documents to be filed in this Section include:** **Copy of other agreements as applicable:** • **Material Transfer Agreements (MTA)** • **Data Sharing/Transfer Agreements** • **Pharma Contract for provision of Drug and/or Funding** • **Insurance/Indemnity (as applicable)** • **Expressions of Interest (EoI)** • **Other Service/Vendor Agreements** *Note: only copies of fully executed agreements should be filed in the TMF.*

Section	Contents	Document Filing Guideline / Comments / Available Templates
17.3	Correspondence with MCRI Legal	**Documents to be filed in this Section include:** • **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	**Documents to be filed in this Section include:** • **A copy of the a trial budget, forecast and actuals** TEMPLATE - Budget *Related Links:* Guideline – Setting up a research budget Sign up to CRDO's "Budgeting for Research" workshop here
18.2	Invoices/Receipts	**Documents to be filed in this Section include:** • **Copies of relevant invoices and receipts pertaining to the study, including per patient payments**
18.3	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence regarding the study budget, invoice tracking, per patient payments, etc.**
19.0	**Other Communication**	
19.1	Newsletters to Sites	**Documents to be filed in this Section include:** • **Copies of Newsletters sent to participating sites**
19.2	Other General Correspondence	**Documents to be filed in this Section include:** • **Other significant general correspondence**
20.0	**Publications/Abstracts**	
20.1	Publications	**Documents to be filed in this Section include:** • **Copies of accepted publications arising from the study**
20.2	Abstracts	**Documents to be filed in this Section include:** • **Copies of any accepted abstracts arising from the study**
21.0	**Clinical Study Report**	
21.1	Clinical Study Report - If applicable	**Existing Placeholders:** • **Final Clinical Study Report**
21.2	Statistical Report	**Documents to be filed in this Section include:** • **Copy of the Statistical Report**

Section	Contents	Document Filing Guideline / Comments / Available Templates
		• **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	**Existing Placeholders:** • **Copy of the registration release/receipt of the entry from the Registry** *Related Links:* Contact CRDO at crdo.info@mcri.edu.au for assistance with registering your trial
22.2	Updates to Trial Registry: - Annual updates - Updates following change in recruitment status - Posting results	**Documents to be filed in this Section include:** • **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	**Documents to be filed in this Section include:** • **All significant correspondence regarding trial registration**
23.0	**Archiving**	
23.1	Archiving Details	**Documents to be filed in this Section include:** • **Investigator Agreement to Archive Template**
23.2	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence regarding trial achiving**

FOR DRUG & DEVICE TRIALS ONLY		
24.0	**Reference Safety Information for each Investigational Product (Drug/Device Trials Only)** *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	**Documents to be filed in this Section include:** • **Full copy of the Investigator Brochure (IB); or** • **Full copy of the Product Information (PI)** • **Copies of any Associated Documents** e.g. IB Addendums etc *Related documents:*

		SOP: Investigator's Brochure Content, Design, Amendments, Filing & Distribution
24.2	IB Version Tracker	**Documents to be filed in this Section include:** • **IB Version Tracker** *Note: The IB Version Tracker is maintained by the Trial Coordinator and is used to identify the current version of the IB, date of the IB and distribution of the document to all participating sites. If your trial involves multiple drugs/agents, then maintain one tracker per drug/agent.*
24.3	IB Signature Pages (if applicable)	**Documents to be filed in this Section include:** • **IB Signature Pages signed by Sponsor-Investigator** – if applicable *Note: Some IBs require the Sponsor-Investigator to acknowledge receipt of the current IB by signing the signature page contained within the IB. In some instances, a separate Acknowledgement of Receipt may require signing by the Sponsor-Investigator. If applicable, file fully executed documents here.*
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	**Documents to be filed in this Section include:** • **Any correspondence with Drug Company relating to IP manufacturing or importation, if applicable** • **IP Quality Control Release Documentation relating to the batch of IP supplied for the trial.**
25.2	IP Ordering Information / Drug Order Form	**Existing Placeholders:** • **Instructions/Process for ordering IP i.e. via IWRS, if applicable** • **Copy of the Drug Order form used by participating sites to order IP.**
25.3	IP Packaging and Labelling	**Existing Placeholders:** • **Copy of the Secondary Label** • **Secondary Label Approval Form – signed by Sponsor-Investigator, Pharmacy Representative and Sponsor Representative** **Other Documents to be filed in this Section include:** • **Copy of the Primary Label, if applicable** *Related Links:* Guide to Good Manufacturing Practice (GMP) for medicinal products annexes *Note: The generation of Secondary Labels for IPs used in clinical investigations are the responsibility of the Sponsor.*

		Secondary Labels need to be generated in accordance with Annex 13 of the Guide to Good Manufacturing Practice for Medicinal Products – Manufacture of Investigational Medicinal Products.
25.4	Instructions for Handling IP and Trial Related Materials - Pharmacy Manual	**Existing Placeholders:** • **Pharmacy Manual** **Other Documents to be filed in this Section include:** • **Any Other IMP Handling Instructions, if applicable**
25.5	Documentation of Central IP Shipment	**Documents to be filed in this Section include:** • **Import Permits** e.g. AQIS Import Permit, if applicable • **Shipping Records** – usually located in Pharmacy Folder • **Import Letter** – study specific, signed by Sponsor/ Sponsor-Investigator *Note: These tasks are generally delegated to the Distribution Group/Third Party assigned with shipping the drug/IP from the Drug Company to either a "Central Pharmacy" or the participating site themselves.* *Note: In the Comments column of the TMF Table of Contents write "All IMP related activities have been delegated by Sponsor to Central Pharmacy or Site Pharmacy – documents located in Central or Site Pharmacy folder."*
25.6	Documentation of Central IP: - Quarantines - Returns - Destructions/Drug Destruction Form	**Existing Placeholders:** • **Drug Destruction Form Template** • **Process for the reporting of any IP Deviations (i.e. temperature excursions, IP complaints, IP quarantines) and associated forms** • **Process for the Return/Destruction of any unsed IP at the end of the study** *Note: In the Comments column of the TMF Table of Contents, indicate that site-specific Drug Destruction Forms are filed in section 23.4 of the corresponding Site Investigator File (SIF), but not until the end of the study, as they will be filed in Pharmcy until the study end.*
25.7	Documentation of Central IP Dispensing: - Accountability and Reconciliation (used/unused/destroyed) - Drug Accountability Log Templates	**Existing Placeholders:** • **Bulk Drug Accountability Log Template** • **Individual Drug Accountability Log Template** *Note: In the Comments column of the TMF Table of Contents, indicate that site-specific Accountability Logs are filed in section 23.2 of the corresponding Site Investigator File (SIF), but not until the end of the study, as they will be filed in Pharmcy until the study end.*

25.8	Copies of Material Safety Data Sheets (MSDS)	**Existing Placeholders:** • **Copy of the Material Safety Data Sheet (MSDS) for each drug/IP used in the study.** *Note: Copies of MSDS are obtained directly from the Drug Company supplying the IMP.*
25.9	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to the Investigational Product/s.**