Document Management during the Trial

Document	Comments	Investigator's File	Send to Sponsor?	Send to REB?
Training Records	Document all study training received by all study personnel, including self-review.	Yes, originals	As per Sponsor requirements	No
Delegation/Signature Log	Update as staff and activities change.	Yes, original	Yes, copies	No
Screening/Enrollment Log	Documents screening activity (those patients who were screened for the study) and subject enrollment (those enrolled). Paper is preferable as it shows a distinct audit trail that cannot be tracked electronically (Health Canada prefers handwriting and signatures)	Yes, original	As per Sponsor requirements	No
Informed Consent Forms (signed)	Keep originals in a secure location. Participants to receive signed and dated copy before study procedures begin.	Yes, originals	No, but will review during monitoring	No
Participant Code List	Matches participant codes with participant identifiers (personal health information)	Yes	No	No
Electronic data queries or data clarification forms (DCFs).	Resolve data query in electronic system – this will show audit trial. Sign-off may be required by PI/designate. Paper DCFs- resolve and have PI/designate sign/date.	Electronic: n/a Paper DCF: file copy at site	Electronic: n/a Paper DCF: send original to Sponsor	No
SAEs (local)	Report to sponsor within 24 hours. Report to REB as per their reporting requirements. PI must assign causality and severity and sign/date REB and sponsor forms.	Reports for Sponsor and REB filed	Sponsor specific SAE reporting forms completed and sent	REB specific reporting forms completed and sent
SAEs (nonlocal) and other safety reports	Have PI and other staff (as applicable) review. Examples Include Medwatch and/or CIOMS reports.	Yes	N/A (Sponsor generated)	Report to REB as per their requirements
Accountability Records (investigational product)	Documents shipment dates, conditions, tracking and accountability. Sign and date, noting any discrepancies. Records may be completed and housed by pharmacy.	Yes, originals	Yes, copies	No
Shipment Records (study supplies)	Documents shipment dates, conditions, tracking and accountability. Sign and date, noting any discrepancies.	Yes, original	Yes, copies	No
Investigator Brochure/ Product Monograph Updates	Ensure investigators and other affected staff (e.g. pharmacy) review this information and document their review.	Yes	N/A	Yes, requires approval
Informed Consent Form Revisions/Addendums	Sponsor must approve all changes and addendums before REB submission. When a consent form changes the version number and/or date must also change. All addendums have version number and/or date as well.	Yes (retain all versions and addendums)	Yes	Yes, requires REB approval **before use**
Protocol Amendment(s) Protocol Signature Page (PSP)	Should be signed by PI and sponsor. Ensure all staff impacted by amendment review and document their review. Not to be implemented before REB approval unless participant safety requires immediate implementation.	1 signed original PSP	Yes, 2ND signed original OR Scanned PSP "certified copy" as required by Sponsor)	REB must approve amendment **before use,** but not PSP
No Objection Letter (issued by Health Canada)	Required for protocol amendments. Request copy form sponsor as applicable. Not required for phase 4 trials.	Yes	N/A (originates from Health Canada)	Yes, requires approval
Correspondence: REB	File according to date. All documents sent to REB and received from the REB, including approval letters. Electronic copies of documents are acceptable with a Note to File to indicate where the document is saved.	Yes	As per sponsor specifications	N/A
Correspondence : Sponsor	File according to date. Includes monitoring visit letters (pre and post visit) newsletters, protocol clarification memos, relevant e-mails and any documented telephone conversations.	Yes	N/A	No
Qualifications of Investigator and Research Staff	Required for all staff listed on the delegation log. Investigators must provide a current CV and copy of license. Other staff must provide the same or equivalent. CVs must be no older than 2 years at study start and must be signed and dated.	Yes, filed with original signatures and dates or use certified copies	As per sponsor requirements	No
Accreditation/ Reference Ranges Updates	Reference ranges must be updated at least every year.	Yes	If local lab being used copy sent.	N/A

Pre-Trial Document Management

Document	Comments	Investigator File	Send to Sponsor?	Send to REB?
Confidentiality Agreement	PI reviews and signs. May be part of contract or separate agreement.	Copy filed	Yes	No
Protocol Signature Page (PSP)	To be signed by PI and sponsor.	1 signed original.	Yes, 2nd signed original or Scanned "certified copy" as required by Sponsor	No
Qualified Investigator's Undertaking (QIU)	Have PI sign. Required for all drug trials in Canada (phase 1-4)	Yes, original	Yes, As per Sponsor specifications	No
1572	When working with US Sponsors, they might request PI sign. Do not have PI sign this document. Form pertains to US regulations and a Canadian PI cannot confirm s/he will be complaint with US CFR as indicated on form. Contact Research, Innovation and Discovery for support.	Yes	Yes	No
Accreditation and Reference Ranges	A certificate of accreditation and reference ranges is required for the lab(s) used for analysis of study specimens. If central lab is used sponsor will provide copy of accreditation and reference ranges. Reference ranges must be updated annually.	Yes	If local lab being used copy sent to Sponsor	No
Delegation /Signature Log	All significant trial-related duties delegated by the PI must be documented on the delegation log before the duties are assumed.	Yes, original	Yes, copy. Copies will be required as updates made	No
Qualifications of Investigator and Research Staff	Required for all staff listed on the delegation log. Investigators must provide a current CV and copy of license. Other staff must provide the same or other equivalent. CVs must be no older than 2 years at study start and must be signed and dated.	Yes, filed with original signatures and dates or use certified copies	As per sponsor requirements	As per REB specifications. CV of PI is required with initial submission
Informed Consent Form	Merge sponsor template with REB template. Sponsor must approve all changes before REB submission. Each time the consent form changes the version number and/or date must also change.	Yes	Yes, sponsor must approve changes **before** submission to REB.	Yes, requires approval
Information for Participants	All written information to be given to participants needs to be approved by REB before use. This includes advertisements, teaching aids, contact information and/or documents for data collection.	Yes	If site generated, need sponsor approval before submitting to REB.	Yes, requires approval
Protocol (final version)	Ensure investigators and staff review the protocol as required to fulfill their study roles and that this review or other form of training is documented.	Yes	N/A (originates with Sponsor)	Yes, requires approval
Investigator's Brochure (IB)/ Product Monograph (PM)	Ensure investigators and research staff (as applicable, e.g. pharmacy) review as required to fulfill their study duties and have hard copies or electronic copies for reference.	Yes	N/A (provided by Sponsor)	Yes, requires approval
Investigator's Brochure/Product Monograph Acknowledgment	Sponsor will provide this document for the PI to sign/date to acknowledge receipt and review of the IB/PM	Yes	Yes	No
No Objection Letter (issued by Health Canada)	May need to request copy from sponsor, if not provided. Required for all clinical trials and protocol amendments. Required for all phase 1-3 drug trials in Canada. Not required for phase 4 trials.	Yes	N/A (originates from Health Canada)	Yes
Financial Aspects of Study (Budget), Study Agreement and Insurance Statement.	These may be separate documents or together as one contract. The content of such documents depends on the requirements of the investigator, REB and/or institution.	1 signed original	2ND signed original OR scanned "certified copy as required by the Sponsor	As per REB specifications
REB Approval Letter and other correspondence	Letter must state full approval and specify time period for approval. Contains Research Ethics Board Attestation (REBA).	Yes	Yes, copy sent ASAP	N/A
REB Membership List	Generated by REB upon initial review.	Yes	Yes	N/A
Site Initiation Visit Report	Documents that trial procedures were reviewed with research staff.	Yes	N/A	No
Shipping Records (study supplies)	Sign and date noting any discrepancies. Document shipment dates, conditions, tracking and accountability.	Yes, original	Yes, copies	No
Accountability Records (investigational product)	Documents shipment dates, conditions, tracking and accountability. Sign and date noting any discrepancies. Records may be completed and housed by pharmacy.	Yes	Yes	No
Decoding Procedures for Blinded Trials	If not adequately described in the protocol these instructions may be housed separately. Required for emergency situations where un-blinding is required.	Yes	N/A	No