Abbreviated List of Essential Study Documents for a Clinical Trial

Essential Documents are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements.*

** http://ichgcp.net/8-essential-documents-for-the-conduct-of-a-clinical-trial*

List of Essential Study Documents for conducting a clinical research study at the site level		
DOCUMENT	**PURPOSE**	**COMMENTS**
REQUIRED		
Signed Protocol & Amendments	To ensure everyone is aware and has reviewed study details	
Any information given to a study participant, including a Research Ethics Board (REB) approved informed consent, PLUS copies of all signed informed consent forms	To document that information provided to the participant has been approved by the REB, and that all participants have documented their agreement to participate	
REB approval of protocol & amendments, CRF, ICF, other documents given to the participant	To ensure the study has been reviewed & approved by a research ethics board	
Contract(s) and/or Budget	To ensure all parties understand their responsibilities	
CV and licenses	To document qualifications of all trial staff	Training certificates should be included as well (e.g. GCP)
Institutional /Organizational Approval		Through the REB
Administrative Logs: • Screening Log • Enrollment Log • Delegation Log • Training Log • Protocol Deviation Log	To document: • Who was screened and did not pass screening • Enrollment into the study • Appropriately qualified team members' tasks • Training (GCP, TCPS 2, protocol) • Where the protocol was not followed	Or certificates
Copies of the Case Report Forms	To document approved data collection elements	
Relevant Correspondence	To document discussions & decisions	
Source Documentation	To ensure the integrity of the data collected	
IF APPLICABLE		
Site Initiation Report / Monitoring Visit Reports	To document that trial procedures were reviewed with the investigator and trial staff, & any findings of the	

	study monitor	
Health Canada (regulatory) approval		NOL
Unblinding Procedures for blinded trials	To determine what product the participant is receiving in case of emergency	
INVESTIGATIONAL PRODUCT (if applicable)		
IP accountability	To document the IP has been used according to the protocol	
Temperature Logs	To document storage conditions were met	
Safety Information (Investigators Brochure, or Product Monograph), including all updates	For use in the assessment of adverse events	