

The following template is geared to Clinical Trials. However, where appropriate, this template can be used for other types of studies by eliminating irrelevant categories.

**Before the Clinical Phase of the Trial Commences**

During this planning stage the following documents should be generated and should be on file before the trial formally starts

Title of Document	Purpose	Located in the files of		
		Investigator	Sponsor	IRB
<b>INVESTIGATOR BROCHURE</b>	To document that relevant and current scientific information about the investigational product has been provided to the investigator	X	X	X
<b>SIGNED PROTOCOL, AMENDMENTS, IF ANY, &amp; SAMPLE CRF</b>	To document Investigator and Sponsor agreement to the protocol/amendment(s) and CRF	X	X	X
<b>INFO. GIVEN TO TRIAL SUBJECT</b>		X	X	X
- <b>INFORMED CONSENT FORM</b>	Including all applicable translations to document the informed consent	X	X	X
- <b>ANY OTHER WRITTEN INFORMATION</b>	To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent	X	X	X
- <b>ADVERTISEMENT FOR SUBJECT RECRUITMENT</b>	(if used) To document that recruitment measures are appropriate and not coercive	X	X	X
<b>FINANCIAL ASPECTS OF THE TRIAL</b>	To document the financial agreement between the Investigator/institution and the Sponsor for the trial	X	X	X*
<b>INSURANCE STATEMENT</b>	(where required) To document that compensation to subject(s) for trial-related injury will be available	X	X	
<b>SIGNED AGREEMENT BETWEEN INVOLVED PARTIES</b>	To document agreements. e.g.: Investigator/institution & Sponsor - Investigator/institution & CRO - Sponsor & CRO - Investigator/institution & authority(ies)	X	X	X*
<b>DATED, DOCUMENTED APPROVAL/ FAVORABLE OPINION OF IRB/ IEC OF THE FOLLOWING:</b>	To document that the trial has been subject to IRB/IEC review and given approval/favorable opinion and to identify the version number and date of the document(s)	X	X	X
- protocol and any amendments		X	X	X
- CRF (if applicable)		X	X	X
- informed consent form(s)		X	X	X
- any written information to be provided to the subject(s)		X	X	X
- advertisement for subject recruitment (if used)		X	X	X
- subject compensation (if any)		X	X	X
- any other documents given approval/ favorable opinion		X	X	X

Title of Document	Purpose	Located in the files of		
		Investigator	Sponsor	IRB
<b>IRB/INDEPENDENT ETHICS COMMITTEE COMPOSITION</b>	To document that the IRB/IEC is constituted in agreement with GCP	X	X	
<b>1. CV AND/OR OTHER DOCUMENTS EVIDENCING QUALIFICATIONS OF INVESTIGATOR(S) AND SUB-INVESTIGATOR(S) and</b> <b>2. VERIFICATION OF HUMAN SUBJECTS TRAINING</b>	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects	X	X	X^
<b>NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/TECHNICAL PROCEDURE(S) AND/OR TEST(S) INCLUDED IN THE PROTOCOL</b>	To document normal values and/or ranges of the tests	X	X	
<b>MEDICAL/LABORATORY/TECHNICAL PROCEDURES /TESTS</b> - certification or - accreditation or - established quality control and/or external quality assessment or - other validation*	To document competence of facility to perform required test(s) , and support reliability of results	X	X	
<b>SAMPLE OF LABEL(S) ATTACHED TO INVESTIGATIONAL PRODUCT CONTAINER(S)</b>	To document compliance with applicable labeling regulations and appropriateness of instructions provided to the subjects	X	X	
<b>INSTRUCTIONS FOR HANDLING OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS</b> (if not included in protocol or Investigator Brochure)	To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational products and trial-related materials	X	X	
<b>SHIPPING RECORDS FOR INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS</b>	To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial-related materials and allows tracking of product batch, review of shipping conditions, and accountability	X	X	
<b>CERTIFICATE(S) OF ANALYSIS OF INVESTIGATIONAL PRODUCT(S) SHIPPED</b>	To document identity, purity, and strength of investigational product(s) to be used in the trial		X	
<b>DECODING PROCEDURES FOR BLINDED TRIALS</b>	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subjects' treatment	X	X**	
<b>MASTER RANDOMIZATION LIST</b>	To document method for randomization of trial population		X**	
<b>PRE-TRIAL MONITORING REPORT</b>	To document that the site is suitable for the trial	X	X	
<b>TRIAL INITIATION MONITORING REPORT</b>	To document that trial procedures were reviewed with the Investigator and the Investigator's trial staff	X	X	

**During the Clinical Conduct of the Trial**

In addition to having on file the above documents, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available

Title of Document	Purpose	Located in the files of		
		Investigator	Sponsor	IRB
<b>INVESTIGATOR BROCHURE/PRODUCT DESCRIPTION UPDATES/</b>	To document that Investigator is informed in a timely manner of relevant information as it becomes available	X	X	X
<b>ANY REVISION TO:</b>	To document revisions of these trial related documents that take effect during trial			
- protocol/amendment(s) and CRF		X	X	X
- informed consent form		X	X	X
- any written information provided to subjects		X	X	X
- advertisement for subject recruitment (if used)		X	X	X
<b>DATED, DOCUMENTED APPROVAL/ FAVORABLE OPINION OF IRB/(IEC OF THE FOLLOWING:</b>	To document that the amendment(s) and/or revision(s) have been subject to IRB/IEC review and were given approval/favorable opinion and to identify the version number and date of the document(s)	X	X	
- protocol amendment(s) - revision(s) of: - informed consent form- any other written information to be provided to the subject - advertisement for subject recruitment- any other documents given approval/favorable opinion- continuing review of trial*				
<b>REGULATORY AUTHORITY(IES) AUTHORIZATIONS/APPROVALS/ NOTIFICATIONS WHERE REQUIRED FOR:</b>	To document compliance with applicable regulatory requirements	X	X	
- protocol amendment(s) and other documents				
<b>CVs FOR NEW INVESTIGATOR(S) AND/OR SUB-INVESTIGATOR(S)</b>		X	X	
<b>UPDATES TO NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/LABORATORY/ TECHNICAL PROCEDURE(S)/TEST(S) INCLUDED IN THE PROTOCOL</b>	To document normal values and ranges that are revised during the trial	X	X	
<b>UPDATES OF MEDICAL/LABORATORY/ TECHNICAL PROCEDURES/TESTS</b>	To document that tests remain adequate throughout the trial period	X	X	
- certification or - accreditation or - established quality control and/or external quality assessment or - other validation (where required)				
<b>DOCUMENTATION OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS SHIPMENT</b>		X	X	

Title of Document	Purpose	Located in the files of		
		Investigator	Sponsor	IRB
<b>CERTIFICATE(S) OF ANALYSIS FOR NEW BATCHES OF INVESTIGATIONAL PRODUCTS</b>			X	
<b>MONITORING VISIT REPORTS</b>	To document site visits by, and findings of, the monitor	X	X	
<b>RELEVANT COMMUNICATIONS OTHER THAN SITE VISITS</b> - letters - meeting notes - notes of telephone calls	To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE) reporting	X	X	
<b>SIGNED INFORMED CONSENT FORMS</b>	To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each subject in trial and to document direct access permission	X	X	X
<b>SOURCE DOCUMENTS</b>	To document the existence of the subject and substantiate integrity of trial data collected and to include original documents related to the trial, to medical treatment, and history of subject	X	X	
<b>SIGNED, DATED AND COMPLETED CASE REPORT FORMS (CRF)</b>	To document that the Investigator or authorized member of the Investigator's staff confirms the observations recorded	X copy	X orig.	
<b>DOCUMENTATION OF CRF CORRECTIONS</b>	To document all changes/additions or corrections made to CRF after initial data were recorded	X copy	X orig.	
<b>NOTIFICATION BY ORIGINATING INVESTIGATOR TO SPONSOR OF SERIOUS ADVERSE EVENTS AND RELATED REPORTS</b>	Notification by originating Investigator to Sponsor of serious adverse events and related reports	X	X	
<b>NOTIFICATION BY SPONSOR AND/OR INVESTIGATOR, IF NEEDED, TO REGULATORY AUTHORITY(IES) AND IRB OF UNEXPECTED SERIOUS ADVERSE REACTIONS AND OF OTHER SAFETY INFORMATION</b>	Notification by Sponsor and/or Investigator, where applicable, to regulatory authorities and IRB(s)/IEC(s) of unexpected serious adverse drug reactions	X*	X	X
<b>NOTIFICATION BY SPONSOR TO INVESTIGATORS OF SAFETY INFORMATION</b>	Notification by Sponsor to Investigators of safety information	X	X	X
<b>PERIODIC REPORTS TO IRB</b>	Interim or annual reports provided to IRB	X	X*	X
<b>SUBJECT SCREENING LOG</b>	To document identification of subjects who entered pre-trial screening	X	X	
<b>SUBJECT IDENTIFICATION CODE LIST</b>	To document that Investigator/institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial and allows Investigator/institution to reveal identity of any subject	X	X*	

Title of Document	Purpose	Located in the files of		
		Investigator	Sponsor	IRB
<b>SUBJECT ENROLLMENT LOG</b>	To document chronological enrolment of subjects by trial number	X		
<b>INVESTIGATIONAL PRODUCTS ACCOUNTABILITY AT THE SITE</b>	To document that investigational product(s) have been used according to the protocol	X	X	
<b>SIGNATURE SHEET</b>	To document signatures and initials of all persons authorised to make entries and/or corrections on CRFs	X	X	
<b>RECORD OF RETAINED BODY FLUIDS/ TISSUE SAMPLES (IF ANY)</b>	To document location and identification of retained samples if assays need to be repeated	X	X	
<b>After Completion or Termination of the Trial</b>				
After completion or termination of the trial, all of the documents identified previously should be in the file together with the following				
<b>INVESTIGATIONAL PRODUCT(S) ACCOUNTABILITY AT SITE</b>	To document that the investigational product(s) have been used according to the protocol and to document the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to Sponsor	X	X	
<b>DOCUMENTATION OF INVESTIGATIONAL PRODUCT DESTRUCTION</b>	To document destruction of unused investigational products by Sponsor or at site	X***	X	
<b>COMPLETED SUBJECT IDENTIFICATION CODE LIST</b>	To permit identification of all subjects enrolled in the trial in case follow-up is required. (list should be kept in a confidential manner and for agreed upon time)	X	X	
<b>AUDIT CERTIFICATE</b>	(if available) To document that audit was performed	X	X	
<b>FINAL TRIAL CLOSE-OUT MONITORING REPORT</b>	To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files	X	X	
<b>TREATMENT ALLOCATION AND DECODING DOCUMENTATION</b>	Returned to Sponsor to document any decoding that may have occurred	X	X	
<b>FINAL REPORT BY INVESTIGATOR TO IRB</b>	To document completion of the trial	X	X	X
<b>CLINICAL STUDY REPORT</b>	To document results and interpretation of trial	X*	X	

\*If applicable / required

\*\* Third party if applicable

\*\*\* If destroyed at the site

^ For principal investigators, co-investigators and sub-investigators, and all key research personnel. Must submit CV/resume for investigators, and verification of Human Subject Training for all (investigators and research personnel) to the IRB.