Sponsor-annotated modification using the ICH List of Essential Documents

Investigator Name:	
Study:	

	Title of Document	Relevant details, version dates, revision dates	Present at site	Present at sponsor	Notes
1	Investigator's Brochure	Original issued _____, no updates			
2	Signed protocol and amendments, if any, and sample case report form (CRF)	Original protocol dated _____, amendment dated _____, no CRF amendments			
3	Information given to trial subject	Original approved by IRB _____			
	-Informed consent form (including all applicable translations)	Subject information sheet approved by IRB _____			
	-Any other written information				
	-Advertisement for subject recruitment (if used)	No advertising used for this study			
4	Financial aspects of the trial	Certification of no financial interest provided on _____			
5	Insurance statement (where required)	Contract between investigator and sponsor dated _____			
6	Signed agreement between involved parties, e.g.,	Contract between investigator and sponsor dated _____			
	-Investigator / institution and sponsor				
	-Investigator / institution and CRO				
	-Sponsor and CRO				
	-Investigator / institution and authority(ies) (where required)				

7	Dated, documented approval / favorable opinion of IRB of the following:	Original IRB approval document dated _____. No IRB continuing review; study closed in *11* months			
	-Protocol and any amendments				
	-CRF (if applicable)				
	-Informed consent form(s)				
	-Any other written information to be provided to the subject(s)				
	-Advertisement for subject recruitment (if used)				
	-Subject compensation (if any)				
	-Any other documents given approval/favorable opinion				
8	Institutional review board / independent ethics committee composition	List provided with IRB approval _____		When required	
9	Regulatory authority(ies) authorization / approval / notification of protocol	Not applicable to this study	When required	When required	
10	Curriculum vitae and/or other relevant documents evidencing qualifications of investigator(s) and sub-investigators	CV for PI dated _____;CV for sub-investigator R. Smith, dated _____; no investigators added			
11	Normal value(s) / range(s) for medical/laboratory / technical procedure(s) and/or test(s)	Provided by Central Lab dated _____, no updates			
12	Medical / laboratory / technical procedures / tests	Provided by Central Lab dated _____, no updates	When required		
	-Certification or				
	-Accreditation or				
	-Established quality control and/ or external quality assessment or				
13	Sample of label(s) attached to investigational product container(s)	One double-blind label			

14	Instructions for handling of investigational product(s) and trial-related materials (if not included in protocol or Investigator's Brochure)	Included in Investigator's Brochure			
15	Shipping records for investigational product(s) and trial-related materials	Shipping document dated _____			
16	Certificate(s) of analysis of investigational product(s) shipped	Dated _____	Not required		
17	Decoding procedures for blinded trials	In protocol			
18	Master randomization List		Not required		
19	Pretrial monitoring report	Dated _____			
20	Trial initiation monitoring report	Dated _____			
21	Relevant communications other than site visits	Letters dated: _____, _____, _____, _____, _____, _____, _____, _____			
	-Letters				
	-Meeting notes				
	-Notes of telephone calls				
22	Signed informed consent forms	Each subject screened using procedures		Not required	
23	Source documents	For each subject with data		Not required	
24	Signed, dated, and completed case report forms (CRFs)	For each subject with data	Copy	Original	
25	Documentation of CRF corrections	CRF correction logs dated _____ and _____	Copy	Original	
26	Notification by originating investigator to sponsor of serious adverse events and related reports	SAE reports dated: _____ for subject *X* and _____ subject *X*			

27	Notification by sponsor and/or investigator, where applicable, to regulatory authority(ies) and IRB(s) of unexpected serious adverse drug reactions and other safety information	SAE report to IRB by investigator dated _____. IND safety report filed to the FDA and all other investigators dated _____.	When required		
28	Notification by sponsor to investigators of safety information	IND safety report dated _____			
29	Interim or annual reports to IRB and authority(ies)	Final report to IRB dated _____		When required	
30	Subject screening log	Includes _____subjects		When required	
31	Subject identification code	Includes _____ subjects		Not required	
32	Subject enrollment log	Includes _____subjects		Not required	
33	Investigational product(s) accountability at the site	Includes _____subjects			
34	Signature sheet	Includes PI, sub-investigator, and clinical research coordinator			
35	Record of retained body fluids/ tissues samples (if any)	None			
36	Investigational product(s) accountability at site	Drug disposition record for *XX* subjects			
37	Documentation of return of investigational product(s)	Report date: _____	Unless destroyed at site		
38	Completed subject identification code list	Includes XX subjects		Not required	
39	Audit certificate (if required)	None	Not required		
40	Final audit close-out monitoring report	Report date: _____	Not required		
41	Treatment allocation and decoding documentation	Report date: _____	Not required		
42	Final report by investigator / institution to IRB where required, and where applicable, to the regulatory authority(ies)	Report date: _____		Not required	
43	Clinical Study Report	Report date: _____	If applicable		

NOTES:	