

## Essential Documents for Conduct of Clinical Trial: Checklist

### Documents Before the Clinical Phase of the Trial Commences:

Title of the document		Purpose	Located in files of:			
			ISF	Sponsor	CRO	IEC
1	Investigator's brochure	To document that relevant and current scientific information about the investigational product has been provided to the investigator	✓	✓	✓	✓
2	Signed protocol & amendments, if any, and sample case report form (CRF)	To document investigator and sponsor agreement to the protocol/amendment(s) and CRF	✓	✓	✓	✓
3	Information given to trial subject: <ul style="list-style-type: none"> <li>informed consent form (including all applicable translations)</li> </ul>	To document the informed consent	✓	✓	✓	✓
4	Any other written information	To document that subjects will be given appropriate information (content and wording) to support their ability to give fully informed consent	✓	✓	✓	✓
5	Advertisement for subject recruitment (if used)	To document that recruitment measures are appropriate and not coercive	✓	✓	✓	✓
6	Financial aspects of the trial	To document the financial agreement between the investigator/institution and the sponsor for the trial	✓	✓	✓	✓

7	Insurance statement (where required)	To document that compensation to subject(s) for trial-related injury will be available	✓	✓	✓	✓
8	Dated, documented approval / favorable opinion of independent ethics committee (IEC) of the following: <ul style="list-style-type: none"> <li>• protocol and any amendments</li> <li>• CRF (if applicable)</li> <li>• informed consent form(s)</li> <li>• any other</li> <li>• written information to be provided to the subject(s)</li> <li>• advertisement</li> <li>• for subject recruitment (if used)</li> <li>• Subject compensation (if any)</li> <li>• any other documents given approval / favorable opinion</li> </ul>	To document that the trial has been subject to IEC review and given approval / favorable opinion. To identify the version number and date of the document(s)	✓	✓	✓	✓
9	Independent Ethics Committee composition	To document that the IEC is constituted in agreement with GCP	✓	✓	✓	✓
10	Regulatory authority(ies) authorisation / approval / notification of protocol (where required)	To document appropriate authorisation / approval / notification by the regulatory authority(ies) has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s)	✓	✓	✓	✓
11	Curriculum vitae and/or other relevant documents evidencing qualifications of Investigator(s) and Co-Investigator / Sub-Investigator(s)	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects	✓	✓	✓	✓

12	Normal value(s) / range(s) for medical / laboratory / technical procedure(s) and/or test(s) included in the protocol	To document normal values and/or ranges of the tests	✓	✓	✓	N/A
13	Sample of label(s) attached to investigational product container(s)	To document compliance with applicable labelling regulations and appropriateness of instructions provided to the subjects	✓	✓	✓	N/A
14	Instructions for handling of investigational product(s) and trial-related materials (if not included in protocol or Investigator's Brochure	To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational products and trial-related materials	✓	✓	✓	N/A
15	Shipping records for investigational product(s) and trial-related materials	To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability	✓	✓	✓	N/A
16	Certificate(s) of analysis of investigational product(s) shipped	To document identity, purity, and strength of investigational product(s) to be used in the trial	N/A	✓	✓	N/A
17	Decoding procedures for blinded trials	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subject's treatment	✓	✓	✓	N/A
18	Master randomization list	To document method for randomization of trial population	N/A	✓	✓	N/A
19	Pre-trial monitoring report	To document that the site is suitable for trial (may be combined with Trial initiation monitoring report)	N/A	✓	✓	N/A

20	Trial initiation monitoring report	To document that the trial procedures were reviewed with the investigator and the investigator's trial staff (may be combined with Pre-trial monitoring report)	✓	✓	✓	N/A
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### 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 the document		Purpose	Retained in the file of:			
			ISF	Sponsor	CRO	IEC
21	Investigator's brochure updates	To document that investigator is informed in a timely manner of relevant information as it becomes available	✓	✓	✓	✓
22	Any revision to: - protocol amendment(s) and CRF - informed consent form - any other written information provided to subjects - advertisement for subject recruitment(if used)	To document revisions of these trial related documents that take effect during trial	✓	✓	✓	✓
23	Dated, documented approval / favorable opinion of IEC of the following: - protocol amendment(s) - revision(s) of: - informed consent form - any other written Information provided to subject - advertisement for Subject recruitment(if used) - any other documents given approval / favorable opinion - continuing review of trial (where required)	To document that the trial has been subject to IEC review and given approval / favorable opinion. To identify the version number and date of the document(s).	✓	✓	✓	✓
24	Regulatory authority(ies) authorisations / approvals / notifications where required for: - protocol amendment(s) and other documents	To document compliance with applicable regulatory requirements	✓	✓	✓	✓
25	Curriculum vitae for new investigator(s) and / or sub- investigator(s)	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects	✓	✓	✓	✓

Title of the document		Purpose	Retained in the file of:			
			ISF	Sponsor	CRO	IEC
26	Updates to normal value(s) / range(s) for medical / laboratory / technical procedure(s) / test(s) included in the protocol	To document normal values and ranges that are revised during the trial	✓	✓	✓	N/A
27	Medical / laboratory / technical procedures / tests - certification or - accreditation or - established quality control and / or external quality assessment or - other validation (where required)	To document that tests remain adequate throughout the trial period	✓	✓	✓	N/A
28	Documentation of investigational product(s) and trial-related material shipment	To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability	✓	✓	✓	N/A
29	Certificate(s) of analysis for new batches of investigational products	To document identity, purity, and strength of investigational product(s) to be used in the trial	N/A	✓	✓	N/A
30	Monitoring visit reports	To document site visits by, and findings of, the monitor	N/A	✓	✓	N/A
31	Relevant communications other than site visits - 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	✓	N/A	✓	N/A
32	Signed informed consent forms	To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each subject in trial. Also to document direct access permission	✓ (Original)	✓ (Copy)	✓ (Copy)	N/A
33	Source documents	To document the existence of the subject and substantiate integrity of trial data collected. To include original documents	✓ (Original)	✓ (Copy)	✓ (Copy)	N/A

Title of the document		Purpose	Retained in the file of:			
			ISF	Sponsor	CRO	IEC
		related to the trials, to medical treatment, and history of subject				
34	Signed, dated and completed case report forms (CRF)	To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject	✓ (Copy)	✓ (Copy)	✓ (Copy)	N/A
35	Documentation of CRF corrections	To document all changes / additions or corrections made to CRF after initial data were recorded	✓ (Original)	✓ (Copy)	✓ (Copy)	N/A
36	Notification by originating investigator to sponsor of serious adverse events and related reports	Notification by originating investigator to sponsor of serious adverse events and related reports	✓	✓	✓	✓
37	Notification by sponsor and/or investigator, where applicable, to regulatory authority(ies) and IEC(s) of unexpected serious adverse drug reactions and of other safety information	Notification by sponsor and/or investigator, where applicable, to regulatory authorities and IEC(s) of unexpected serious adverse drug reactions and of other safety information	✓	✓	✓	✓
38	Notification by sponsor to investigators of safety information	Notification by sponsor to investigators of safety information	✓	✓	✓	✓
39	Interim or annual reports to IEC and authority(ies)	Interim or annual reports provided to IEC and to authority(ies)	✓	✓	✓	✓
40	Subject screening log	To document identification of subjects who entered pre-trial screening	✓	✓ (Where required)	✓ (Where required)	N/A
41	Subject identification code list	To document that investigator / Institution keeps a confidential list of names of all subjects allocated to trial	✓	✓	✓	N/A

Title of the document		Purpose	Retained in the file of:			
			ISF	Sponsor	CRO	IEC
		numbers on enrolling in the trial. Allows investigator/ Institution to reveal identity of any subject				
42	Subject enrolment log	To document chronological enrolment of subjects by trial number	✓	✓	✓	N/A
43	Investigational products accountability at the site	To document that investigational product(s) have been used according to the protocol	✓	✓	✓	N/A
44	Signature sheet	To document signatures and initials of all persons authorised to make entries and / or corrections on CRFs	✓	✓	✓	N/A
45	Record of retained body fluids/ tissue samples (if any)	To document location and identification of retained samples if assays need to be repeated	✓	✓	✓	N/A



### After Completion or Termination of the Trial

After completion or termination of the trial, all of the documents identified should be in the file together with the following

Title of the document		Purpose	Retained in the files of:			
			ISF	Sponsor	CRO	IEC
46	Investigational product(s) accountability at site	To document that the investigational product(s) have been used according to the protocol. To documents the final accounting of  investigational product(s) received at the site, dispensed to subjects, return by the subjects, and returned to sponsors	✓	✓	✓	N/A
47	Documentation of investigational product destruction	To document destruction of unused investigational products by sponsor or at site	✓ (if destroyed at site)	✓	✓	N/A
48	Completed subject identification code list	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	✓	✓	✓	N/A
49	Audit certificate (if available)	To document that audit was performed	N/A	✓	✓	N/A
50	Final trial close-out monitoring report	To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files	N/A	✓	✓	N/A
51	Treatment allocation and decoding documentation	Returned to sponsor to document any decoding that may have occurred	N/A	✓	✓	N/A
52	Final report by investigator to IEC where required, and where applicable, to the regulatory authority(ies)	To document completion of the trial	✓	✓	✓	✓
53	Clinical study report	To document results and interpretation of trial	✓	✓	✓	✓