

Annex 1
to the Procedure for Conducting Clinical
Trials of Medicinal Products and Expert
Evaluation of Materials Pertinent to
Clinical Trials

**LIST OF ESSENTIAL DOCUMENTS PERTINENT TO CLINICAL TRIAL
THAT ARE TO BE KEPT AT HCS, TRIAL SITE AND CLINICAL TRIAL
SPONSOR**

	TO BE STORED AT ARCHIVE (FILE) OF	
	investigator/HCS	clinical trial sponsor
1. Prior to clinical trial:		
Investigator's brochure	X	X
Protocol of clinical trial and amendments to it (if any) signed by clinical trial sponsor and investigator	X	X
Sample of case report form	X	X
Materials given to patients (healthy volunteers):	X	X
	X	X
	X	
Informed consent (including the necessary translations);		
Other written information for patient (healthy volunteer);	X	X
Advertisement about study subjects recruitment (if used)	X	
Information about financial aspects of clinical trial	X	X
Insurance contract (certificate to contract)	X (copy of certificate to insurance contract)	X (insurance contract)
Signed contract between the parties:		
Investigator/HCS and clinical trial sponsor;	X	X
Investigator/HCS and		X

contract research organization;	X	(if necessary)
Clinical trial sponsor and contract research organization.		X
Dated and documented approval of the Ethics Committee at HCS pertinent to materials of clinical trial	X	X
Document on composition of the Ethics Committee at HCS	X	X (if necessary)
Center's opinion pertinent to clinical trial	X	X
Curriculum vitae of investigators (CV) and/or other documents which confirm their qualifications	X	X
Normal values/ranges for clinical/laboratory/instrumental tests/investigations envisaged in the clinical trial protocol	X	X
Clinical/laboratory/instrumental tests/investigations: certification or accreditation, or internal and/or external quality control of laboratory equipment, other methods of verification	X	X
Sample of label attached to the investigational medicinal product's container		X
Instructions for handling investigational medicinal product and the required trial-related materials (if not included in clinical trial protocol or investigator's brochure)	X	X
Documents about supply of investigational medicinal product and the required trial-related materials	X	X

Certificate of analysis for batch of the investigational medicinal product		X
Randomized code disclosing procedure for blind clinical trials	X	X
Randomization list		X
Monitor's report about previous visit		X
Monitor's report about starting visit	X	X
2. During the clinical trial:		
Updates and revisions of: Investigator's brochure; Clinical trial protocol and its amendments (if any); Case report form; Informed consent form and written information provided to patients (healthy volunteers); Advertisement about study subject's recruitment (if applicable).	X	X
Dated and documented approval of the Ethics Committee at HCS of: Amendments to clinical trial protocol; Update(s) and revision(s) of: Informed consent and written information provided to patients (healthy volunteers); Advertisement about study subject's recruitment (if used); Results of periodic reviews of documents related to clinical trial	X	X
Center's opinion on substantial amendments to clinical trial protocol	X	X
Updates of normal values/ranges for clinical/laboratory/instrumental	X	X

tests/investigations envisaged in the protocol of clinical trial		
Curriculum vitae of new principal investigator/investigator/co-investigator	X	X
Updates of clinical/laboratory/instrumental test/investigation procedures: certification or accreditation, or internal and/or external quality control, other verification methods	X	X
Documents about supply of investigational medicinal product and required trial-related materials	X	X
Certificates of new batches of investigational medicinal product		X
Monitor's reports		X
Information on negotiations/correspondence related to clinical trial	X	X
Signed informed consent forms	X	
Source medical documents	X	
Completed, dated and signed case report forms of trial subjects	X (copy)	X (original)
Registration of corrections (? updates) in case report forms	X (copy)	X (original)
Investigator's notification of clinical trial sponsor about serious adverse events and related reports	X	X
Notifications about serious unexpected adverse reactions submitted by clinical trial sponsor to the Center	X	X
Interim or annual reports on status of clinical trial submitted to the Center and the Ethics Committee at HCS	X	X (if necessary)
Clinical trial sponsor 's	X	X

notification of investigator about new safety data about investigational medicinal product		
Trial subject screening log	X	X (if necessary)
Trial subject identification code list	X	
Trial subject recruitment log	X	
Investigational medicinal product accounting at clinical trial site	X	X
List of signature samples of principal investigator/investigators/co-investigators	X	X
Log of retained body fluids/tissues samples (if applicable)	X	X
3. After the end of the clinical trial:		
Investigational medicinal product accounting at clinical trial site	X	X
Statement of disposal of unused investigational medicinal product	X (if disposed at clinical trial site)	X
Final trial subject identification code list	X	
Document on conducted audit (if any)		X
Monitor's report about final visit		X
Indicated treatment and decoding information		X
Clinical trial report	X (if necessary)	X

{Annex 1 in wording of the MoH Order № 523 of 12.07.2012; as amended by the MoH Order № 894 of 24.05.2024}