

CHECKLIST FOR CLINICAL TRIAL PROTOCOLS INVOLVING HUMAN SUBJECTS AND GENERATING DATA INTENDED TO BE SUBMITTED TO REGULATORY AUTHORITIES

(Source: ICH Harmonized Tripartite Guideline for Good Clinical Practice 1996)

	Tick (√) if submitted	Comments
GENERAL INFORMATION		
Protocol identifying number and date		
Name and address of sponsor		
Name and institution of investigator/s		
BACKGROUND		
Name and description of investigational product.		
Summary of findings from nonclinical and clinical studies.		
Description and justification for route of administration, dosage, and treatment periods.		
Statement that trial will be conducted in compliance with GCP and other regulator requirements.		
Description of study population.		
Literature review.		
OBJECTIVES AND PURPOSE		
Detailed description of objectives and purpose.		
TRIAL DESIGN		
Statement of primary and secondary endpoints to be measured.		
Description of type / design of trial.		
Measures taken to minimize bias – randomization, blinding.		
Trial treatment(s) and dosage, dosage form, packaging, labeling.		
Expected duration of subject participation.		
Sequence and duration of all trial periods including follow-up, if any.		
Stopping rules / discontinuation criteria for subjects, parts of trial and entire trial.		
Accountability procedure for study products.		
Maintenance of randomization codes and procedures for breaking codes.		
Identification of data to be directly recorded on CRF.		
SELECTION AND WITHDRAWAL OF SUBJECTS		
Inclusion criteria.		
Exclusion criteria.		
Subject withdrawal criteria.		
When and how to withdraw subjects from trial.		
Type and timing of data to be collected from		

	withdrawn subjects.		
	Whether and how subjects are to be replaced.		
	Follow-up on withdrawn subjects.		
	TREATMENT OF SUBJECTS		
	Details on treatments to be administered.		
	Permitted and not permitted medications / treatments during trial.		
	Rescue medication / procedure.		
	How to monitor subject compliance.		
	ASSESSMENT OF EFFICACY		
	Specification of efficacy parameters.		
	Methods and timing for assessment, recording and analysis.		
	ASSESSMENT OF SAFETY		
	Specification of safety parameters.		
	Methods and timing for assessment, recording and analysis.		
	Procedures for getting reports and reporting of adverse events and intercurrent illnesses.		
	Type and duration of follow-up after adverse events.		
	STATISTICS		
	Statistical methods used.		
	Number of subjects to be enrolled including reason and calculation for sample size.		
	Level of significance to be used.		
	Criteria for termination of trial.		
	Procedure for missing, unused and spurious data.		
	Procedure for any deviation from original statistical plan.		
	Selection of subjects to be included in analysis.		
	DIRECT ACCESS TO SOURCE DATA / DOCUMENTS		
	Specify that investigator will permit trial related monitoring, audits, IEC review and regulatory inspection.		
	QUALITY CONTROL AND ASSURANCE		
	ETHICS		
	DATA HANDLING AND RECORD KEEPING		
	FINANCE AND INSURANCE		
	PUBLICATION POLICY		
	SUPPLEMENTS		