

CLINICAL RESEARCH PROTOCOL CHECKLIST

[taken from ICH GCP E6: Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidance, Revision 2 (R2) Nov 2016]

ICH GCP E6, Section 6. CLINICAL TRIAL PROTOCOL AND PROTOCOL

A protocol is a document that describes the background, rationale, objectives, design, methodology, statistical considerations, and organization of a clinical research study. The [ICH Good Clinical Practice Guidelines](#) specify some topics that should generally be included in a protocol. The tool below includes both the ICH GCP recommendations for protocol content with some additional considerations provided by the UW-Madison Health Sciences IRB. Additional information may be provided on separate protocol page(s), or addressed in a separate agreement, and some of the information listed below may be contained in other protocol referenced documents, such as an Investigator's Brochure.

6.1 General Information

E6	Description/Text	Included?	
		Yes	No
6.1.1*	Protocol title, protocol identifying number, and date. Any amendment(s) should also bear the amendment number(s) and date(s).		
6.1.2 *	Name and address of the sponsor and monitor (if other than the sponsor).		
6.1.3	Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor.		
6.1.4	Name, title, address, and telephone number(s) of the sponsor's medical expert (or dentist when appropriate) for the trial.		
6.1.5*	Name and title of the investigator(s) who is (are) responsible for conducting the trial, and the address and telephone number(s) of the trial site(s). <i>*List any collaborating sites where the study will be performed.</i>		
6.1.6	Name, title, address, and telephone number(s) of the qualified physician (or dentist, if applicable) who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).		
6.1.7	Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial.		

6.2 Background Information

E6	Description/Text	Included?	
		Yes	No
6.2.1*	Name and description of the investigational product(s).		
6.2.2*	A summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.		
6.2.3*	Summary of the known and potential risks and benefits, if any, to human subjects.		
6.2.4*	Description of and justification for the route of administration, dosage, dosage regimen, and treatment period(s).		
6.2.5	A statement that the trial will be conducted in compliance with the protocol, GCP, and the applicable regulatory requirement(s).		
6.2.6*	Description of the population to be studied.		
6.2.7*	References to literature and data that are relevant to the trial, and that provide background for the trial.		

6.3 Trial Objectives and Purpose

E6	Description/Text	Included?	
		Yes	No
6.3*	A detailed description of the objectives and the purpose of the trial.		

*Included as a recommended protocol element by the UW-Madison Health Sciences IRB.

6.4 Trial Design

The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design. A description of the trial design should include:

E6	Description/Text	Included?	
		Yes	No
6.4.1*	A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.		
6.4.2	A description of the type/design of trial to be conducted (e.g., double-blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures, and stages. <i>- Definition of when the subject is considered 'enrolled' (on study).</i> <i>*Identify any substudies.</i> <i>*Include a detailed description of number of visits, procedures at each visit, visit windows, and length of study visits for subjects.</i>		
6.4.3	A description of the measures taken to minimize/avoid bias, including (for example): (a) Randomization, (b) Blinding		
6.4.4*	Drugs, supplements, or biologics: A description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s). Also include a description of the dosage form, packaging, and labeling of the investigational product(s). <i>Devices: A description of the trial treatment(s) and the device implantation/application, removal. Also include a description of the device specifications, packaging, and labeling of the investigational product(s).</i>		
6.4.5*	The expected duration of subject participation, and a description of the sequence and duration of all trial periods, including follow-up, if any.		
6.4.6*	A description of the "stopping rules" or "discontinuation criteria" for individual subjects, parts of trial, and entire trial.		
6.4.7*	Accountability procedures for the investigational product(s), including the placebo(s)/sham procedures and comparator(s), if any.		
6.4.8	Maintenance of trial treatment randomization codes and procedures for breaking codes.		
6.4.9	The identification of any data to be recorded directly on the CRFs (i.e., no prior written or electronic record of data), and to be considered to be source data.		
6.4.10	If your study is investigator-initiated and multi-site, refer to Section 7 for additional guidance.		

6.5 Selection and Withdrawal of Subjects

E6	Description/Text	Included?	
		Yes	No
	<i>*Subject identification and recruitment methods.</i>		
6.5.1*	Subject inclusion criteria.		
6.5.2*	Subject exclusion criteria.		
	<i>Describe how the eligibility criteria will be determined</i> <ul style="list-style-type: none"> • <i>Information reported by the subject</i> • <i>Medical record review</i> • <i>Results of screening assessments (e.g. questionnaires, diaries, etc.)</i> 		

6.5.3	Subject withdrawal criteria (i.e., terminating investigational product treatment/trial treatment) and procedures specifying: (a) When and how to withdraw subjects from the trial/investigational product treatment. <ul style="list-style-type: none"> • <i>What if a subject develops an exclusionary condition?</i> • <i>What if a subject begins taking an exclusionary medication?</i> (b) A detailed description of the study withdrawal procedures, including the type and timing of the data to be collected for withdrawn subjects. (c) Whether and how subjects are to be replaced.		
	(d) The follow-up for subjects withdrawn from investigational product treatment/trial treatment.		

6.6 Treatment of Subjects

E6	Description/Text	Included?	
		Yes	No
6.6.1*	The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for subjects for each investigational product treatment/trial treatment group/arm of the trial.		
6.6.2*	Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.		
6.6.3	Procedures for monitoring subject compliance.		

6.7 Assessment of Efficacy

E6	Description/Text	Included?	
		Yes	No
6.7.1	Specification of the efficacy parameters.		
6.7.2	Methods and timing for assessing, recording, and analyzing efficacy parameters.		

6.8 Assessment of Safety

E6	Description/Text	Included?	
		Yes	No
6.8.1	Specification of safety parameters.		
6.8.2*	The methods and timing for assessing, recording, and analyzing safety parameters.		
6.8.3*	Procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses.		
6.8.4	The type and duration of the follow-up of subjects after adverse events.		

6.9 Statistics

E6	Description/Text	Included?	
		Yes	No
6.9.1*	A description of the statistical methods to be employed, including timing of any planned interim analysis(es).		
6.9.2*	The number of subjects planned to be enrolled. In multicenter trials, the number of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.		
6.9.3	The level of significance to be used.		
6.9.4*	Criteria for the termination of the trial.		
6.9.5	Procedure for accounting for missing, unused, and spurious data.		

6.9.6	Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in the protocol and/or in the final report, as appropriate).		
6.9.7	The selection of subjects to be included in the analyses (e.g., all randomized subjects, all dosed subjects, all eligible subjects, evaluate-able subjects).		

6.10 Direct Access to Source Data/Documents

E6	Description/Text	Included?	
		Yes	No
6.10	The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s) by providing direct access to source data/documents.		

6.11 Quality Control and Quality Assurance

E6	Description/Text	Included?	
		Yes	No
6.11	A description of the Quality Control and Quality Assurance processes and measures to be taken		

6.12 Ethics

E6	Description/Text	Included?	
		Yes	No
6.12	Description of ethical considerations relating to the trial.		

6.13 Data Handling and Recordkeeping

E6	Description/Text	Included?	
		Yes	No
6.13*	Description of the Data Handling and Record Keeping processes and measures to be taken *Provide information about confidentiality protections, sharing of data, and disposition of data *Identify information that will be extracted from medical records		

6.14 Financing and Insurance

E6	Description/Text	Included?	
		Yes	No
6.14	Financing and insurance if not addressed in a separate agreement.		

6.15 Publication Policy

E6	Description/Text	Included?	
		Yes	No
6.15	Publication policy, if not addressed in a separate agreement.		

6.16 Supplements

E6	Description/Text	Included?	
		Yes	No
6.16	(NOTE: Since the protocol and the clinical trial/study report are closely related, further relevant information can be found in the ICH Guidance for Structure and Content of Clinical Study Reports.)		

7. Investigator-Initiated Multisite Research Studies

	Description/Text	Included?	
		Yes	No
7.1	Identification of a single site to serve as the lead site/coordinating center for the study. A lead site or coordinating center is typically responsible for coordinating activities at all other sites, receiving and analyzing data, and developing and updating the study protocol as needed.		
7.2	Description of how the lead site/coordinating center will communicate with and disseminate information to other sites/personnel (e.g., regularly scheduled conference calls or meetings, notifications to all sites regarding protocol updates or other changes to the study, etc.)		
7.3	A description of how the lead site/coordinating center will ensure that all participating sites use the same version of the protocol, including a description of the procedures that must be followed in order to amend the protocol.		
7.4	Description of how unanticipated problems, adverse events, noncompliance, and/or new information about the study will be managed, including: <ul style="list-style-type: none"> • What events need to be reported • When reports must be made • How the reports are made • To whom the reports are made • How relevant information about such reports will be disseminated to study sites/personnel, including any changes of protocol 		
7.5	Description of how each site's compliance with the protocol and applicable human subjects regulations will be monitored and who will provide the monitoring		
7.6	Identification of all sites that will be involved in the conduct of the research, including: <ul style="list-style-type: none"> • The role of each site (e.g., subject recruitment, laboratory analyses, data analyses) • Identification of all personnel engaged in human subjects research at each site • Description of any differences among sites in study procedures or subject populations 		
7.7	Description of how potential subjects will be identified and recruited at each site that recruits subjects		
7.8	Description of how informed consent is obtained at each site and who conducts the consent process, including any special processes for subjects who may be non-English speaking, illiterate, or have impaired decision-making capacity.		
7.9	Description of data storage, including: <ul style="list-style-type: none"> • All sites at which data will be stored • What data will be stored at what site(s) • Data security measures • Who will have access to identifiable data • When data will be anonymized or destroyed 		
7.10	If the study involves tissue banking, the protocol should describe: <ul style="list-style-type: none"> • All sites at which samples will be stored • What samples will be stored at what site • How sample confidentiality will be protected • Who will have access to identifiable samples • When samples will be anonymized or destroyed 		