AUDITING
PLATFORM

Risk Assessment Form for Optimising Clinical Trials and Research Projects

Introduction

To fill in this form, please consult the accompanying **User Instructions for the Risk Assessment Form for Clinical Trials According to the Clinical Trial Ordinance (ClinO)**. While the **User Instructions** pertain to clinical trials, they can be adapted for filling in the form to conduct risk assessment on research projects according to the Ordinance on Human Research (HRO). Both the **Risk Assessment Form** and its **User Instructions** were developed by the Auditing Platform of the Swiss Clinical Trial Organisation (SCTO), in consultation and collaboration with other platforms of the SCTO and staff of its Clinical Trial Unit (CTU) network. This first version was released in December 2019. The **User Instructions** enable you to determine the recommended risk assessment strategy for a particular clinical trial you are planning. They are hosted separately at http://www.scto.ch/auditing.

You are welcome to adapt this form to your needs and brand it with your institution's logo. Please send your user feedback to us at auditing@scto.ch, as we hope to continue improving this resource.

Scope of this form

- Performance of risk analysis to develop a risk-based quality management system (QMS) for an investigational trial site, a specific clinical trial or research project.
- According to International Council for Harmonisation, namely its Guideline for Good Clinical Practice (referred to as ICH-GCP E6(R2), it is the *sponsor's responsibility* to assure that an adequate QMS is in place to manage the clinical trial and to address potential risks.
- According to the Declaration of Helsinki and data privacy guidelines, it is the Project Leader's responsibility to assure that an adequate QMS is in place, with which to oversee the project and to address potential risks to the research project.
- This **Risk Assessment Form** should help you to identify such potential risks, to evaluate them, and to develop strategies to overcome them.
- This form is suitable both for Sponsor-Investigators running a study in an academic setting and for research projects that run according to the HRO.

Using this form

This document is made up of two parts:

- Part A: assessing risks at system level (e.g. centre, trial site, or research site level), and
- Part B: assessing risks at trial/project level (e.g. at individual trial level)

Part A may be used as a higher-level document for overseeing the entire trial site or research site, in which case it should be signed off by or agreed upon with the Head of the Trial Site/Research Site. Part A must be (re)evaluated for each project, to ensure it is in accordance with the research focus for that specific trial/ project.

Part B is recommended in for each new clinical trial or research project by the Sponsor-Investigator or Project Leader. Experts from local Clinical Trial Units (CTUs) or Clinical Trial Centres (CTCs) may assist or give advice.

Follow-up

The identified risks that are rated as “high” should be corrected immediately. The corrections should be documented. Risks that are rated as “low” can be addressed at an appropriate time point or it should be explained why no action was required.

The Sponsor-Investigator should set a timeline to periodically review risk control measures (see, GCP 5.0.6) and should report them according to GCP, 5.0.7.

Insert your institution's logo here

Part A: Potential risks at sponsor's clinical trial site and/or general at system level

Sponsor's name, phone, and mailing address: (*or if applicable:* Head of Site, phone and mailing address)	

Risks at systems level					
Description	**Rating**	**Rationale for rating / Comments**	**Risk-minimising measures**	**Action deadline**	**Person responsible**
A1 QMS / Processes					
	☐low ☐high				

A2 Infrastructure / Systems					
	☐low ☐high				
A3 Resources / Personnel					
	☐low ☐high				
A4 Others					
	☐low ☐high				

Sponsor / Sponsor-Investigator / Head of Site	*Full name*
Date and signature	*dd.mm.yyyy and signature*

Insert your institution's logo here

Part B: Specific risks at clinical trial level/research project level

Clinical Trial / Research Project Title	
Project / Trial Number	
Sponsor-Investigator / Project Leader Name, phone and email address	
Site contact	

Risks at project level

Description	Rating	Rationale for rating / Comments	Risk-minimising measures	Action Deadline	Person responsible
B1 Project Design					

	☐low ☐high				
B2 Data Collection / Project-specific Procedures					
	☐low ☐high				
B3 Informed Consent Process / Project participants					
	☐low ☐high				
B4 Participants' Safety					
	☐low ☐high				

B5 IMP and / or Sample Management					
	☐low ☐high				
B6 Trial site(s)					
	☐low ☐high				
B7 Monitoring **(**See also the **Risk-Based Monitoring Score Calculator** available at scto.ch/monitoring)					
	☐low ☐high				
B8 Others					

	☐low ☐high				

Completed by	*Full name*
Role	*Role at trial site or within clinical trial*
Date and signature	*dd.mm.yyyy and signature*

Sponsor / Sponsor-Investigator / Project Leader	*Full name*
Date and signature	*dd.mm.yyyy and signature*

Please note: Add signatures of other relevant staff if needed e.g. Principal Investigator, Head of Site

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