# Standard Operating Procedures for Risk Assessment – CTIMPs

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## 1. Purpose & Scope

1.1 The EU Good Clinical Practice (GCP) Directive 2001/20/EC was introduced to establish standardisation of research activity in Clinical Trials throughout the European Union. It was transposed into UK law as the Medicines for Human Use (Clinical Trials) Regulations 2004 (Sl 2004/1031) which came into force on 1<sup>st</sup> May 2004. The Medicines for Human Use (Clinical Trials) Regulations together with subsequent amendments will be referred to as the Regulations in the rest of this document<sup>2</sup>.

1.2 This SOP describes the processes that are involved for risk assessment of a Clinical Trial of an Investigational or Medicinal Product (CTIMP) at an individual study or trial level.

1.3 The scope of the document is for all schools at the University of Sussex, all members of staff with substantive employment and students registered at the University (including Brighton and Sussex Medical School).

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## 2. Introduction

2.1 Risk assessment is a systematic process of evaluating the potential hazards associated with a study / trial and assessing the likelihood of those hazards occurring and resulting in harm. All studies contain a level of risk inherent to the protocol that relate to safety and rights of the participants and the credibility of results.

2.2 Risk assessment is an ongoing process that must be continually assessed and managed at each stage of a study to ensure the safety, rights and wellbeing of participants and research staff and the integrity of data is considered for the successful completion of the study.

2.3 It is recommended that a full study-specific risk assessment is conducted for every study and that this is clearly documented, minimally evidenced through the study protocol, although ideally as a separate document in its own right (*RGRA1:* is a suggested template for this) and stored in the Trial Study Master File.

2.4 During the Sponsorship review process, risk assessment is conducted and recorded in accordance nB320.09 Tm0 g0 GezBDC q0sonB320.09 Tm0 g0 GezBDC q830

## 3. Responsibilities

#### Chief Investigator

3.1 The Chief Investigator has responsibility for:

- Content and approval of the completed risk assessment document.
- Review of the risk assessment document.
- The CI may delegate the development and review of the risk assessment document to appropriate members of their study team.

### The Sponsor

3.2 The Sponsor has responsibility for undertaking a risk assessment to inform the decision to provide sponsorship to research and developing risk mitigation actions as appropriate.

## 4. Procedure

4.1 The regulatory framework in the UK provides a range of risk adapted approaches that simplify the processes involved in initiating and managing CTIMPs that meet certain risk criteria. The guidance from the MHRA (Medicines and Healthcare products Regulatory Agency) must be followed alongside any other relevant guidance or regulations.

### 4.2 The MHRA document

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• Type A = No higher than the risk of standard medical care

- Type B = Somewhat higher than the risk of standard medical care
- Type C=Markedly higher than the risk of standard medical care

4.3 Examples of types of clinical trials that are covered under these categories 3y2m0[(a)3(d)3(a)[(4)-e1.04 TfBT/F2 11.

GMP	Good Manufacturing Practice					
HRA	Health Research Authority					
ICH	International Council for Harmonisation of Technical Requirements for					
	Pharmaceuticals for Human Use					
IMP	Investigational or Medicinal Product					

<u>ICH E6</u> <u>Guideline for Good Clinical Practice</u> (1996) https://database.ich.org/sites/default/files/E6\_R2\_Addendum.pdf</u>

Medicines and Healthcare products Regulatory Agency (MHRA) (2014, updated 2019 <u>https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials</u>

MHRA Good Clinical Practice Guide, The Stationery Office: London, 2012

<u>Risk proportionate approaches in clinical trials, Recommendations of the expert group on clinical trials</u> for the implementation of Regulation (EU) No. 536/2014 on clinical trials on medicinal products for human use, 25 April 2017

https://ec.europa.eu/health/sites/default/files/files/dinicaltrials/2016\_06\_pc\_guidelines/gl\_4\_resp\_co ntributor\_6.pdf

## Risk Assessment Tool

Study Title:	
Sponsor (if not US):	
Sponsor Reference Number:	
IRAS Reference:	

EudraCT Number:

#### Study limited to working with data (specific project only)

Research tissue bank

Research database

Other research

Staff Present:

#### Section 1 - Risk Assessment of the Investigational Medical Product or Intervention

#### If this study does not involve an IMP check box and proceed to section 2

Where risks associated with the IMP/intervention are somewhat or markedly higher than those of standard medical care (i.e. Type B or Type Ctrials) details regarding specific risks to body systems and proposed methods for dinical monitoring of such risks should be described. The drug risk assessment should be based on available information (e.g. SnPC, Investigator Brochure, British National Formulary other publications)

Risks associated with IMP / intervention:		Justification		
Type A: risk	to that of standard med	lical care		
Type B: risk	than that of standa	ard medical care		
Type C risk	than that of standa	rd medical care		
IMP/Intervention	Body System	Hazard	Risk Likelihood	
	(i.e. System Organ		L=Low M	
	Class)		= Medium H	

Section 1 - Risk Assessment of the Investigational Medical Product or Intervention (continued)

Potential source of harm	Risk Factor Identified	
	Provide details of study-specific	
	considerations/risk concerns	

Risk Likelihood L=Low Section 2 - Risk Assessment of the Medical Device or In vitro Diagnostic (IVD)

#### If this study does not involve a medical device check box and proceed to section 3

Where risks associated with device are higher than normal (i.e. device used outside of CE marking, or device without CE marking) details regarding specific risks to body systems and proposed methods for clinical monitoring of such risks should be described. The device risk assessment should be based on available information (e.g. Investigator Brochure, Device Technical Specification)

Use of the medical device:		Class of Device Justification for classification		cation		
Œ marked device used within its intended purpose(s) Œ marked device which has been modified or will be used outside its intended		Class I or A ( Class IIa or Class IIb or Class III or D	IVD) B VD) ;(IVD) (IVD)			
Non-Œ marked de	evice (IVD)			<b>、</b>		
Device	Body System (i.e. System Organ Class)	Hazard	Risk Likelihood L = Low M= Medium H = High	N	Aitigation	Comments

#### Section 3 – Research Risk Assessment

Mark risk as "N/A" if not relevant for this study. List any other risks identified for this study in "Other" A. Participants'

Rights and Safety

Potential source of harm	Risk Factor Identified Provide details of study-specific considerations/risk concerns	Risk Likelihood L=Low M = Medium H = High	Mitigation Address all concerns identified	FOR RGO USE ONLY Monitoring/audit methods
Participant population -healthy volunteer/patient -age/vulnerable group -rare disease/illness - non-adherence to study intervention				
Enrolment - eligibility criteria (restrictive inclusion/exclusion) - withdrawal - recruitment period - competitive recruitment - enrolment target justified				

Other		
- Phase I considerations		
- Emergency procedures		