Standard Operating Procedures for Risk Assessment – CTIMPs

This is a controlled document
Any printed versions of this document will be classed as uncontrolled

SOP Reference:	SOP/RG04
Version Number:	1.0
Date:	
Effective Date:	

Author Designation:		

1. Purpose & Scope

2. Introduction

RGRA1:

3. Responsibilities

Chief Investigator

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The Sponsor

4. Procedure

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Risk Assessment Tool

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

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

Risks associated with IMP / intervention:			Justification
IMP/Intervention	Body System *(i.e. System Organ Class)*	Hazard	Risk Likelihood

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

Potential source of harm	Risk Factor Identified	Risk Likelihood

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

Use of the medical device:	Class of Device	Justification for classification

Device	Body System *(i.e. System Organ Class)*	Hazard	Risk Likelihood L M	Mitigation	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	Risk Likelihood	Mitigation	FOR RGO USE ONLY Monitoring/audit methods
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