

SOP number	51.043	Version	1.0
Title	Risk Assessment for non-CTIMPs/research projects (co-) Sponsored by NHSGGC		

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SOP category	NHSGGC Sponsor R&I			
Staff Category				
Staff Category	R	A	C	I
Research Governance Manager (RGM)		X		
Sponsor Research Coordinators (SRC)	X			
R&I Systems and Operations Manager	X			
Sponsor Innovation Co-ordinator (SIC)	X			
Senior Research Administrators (SRA)	X			
Sponsor Research Facilitators (SRF)	X			
R&I Pharmacy			X	
R&I Clinical Trials Monitors			X	
R&I Pharmacovigilance (PV) Manager			X	
R&I Pharmacovigilance (PV) Officer			X	
University of Glasgow Research Regulation & Compliance Manager			X	
Project Managers			X	
Chief Investigators			X	
Study data managers			X	
Study Statisticians			X	
Innovation Project Managers			X	

1. Scope

This procedure applies to non-CTIMP research studies where NHSGGC act as the Sponsor, either as a sole sponsor or co-sponsored with the University of Glasgow. For studies where NHSGGC is not the Sponsor, this process is not applicable and the Sponsor process should be followed. For Clinical Trials of Investigational Medicinal Products (CTIMPs) and Clinical Investigations of non-CA marked Medical Devices (CIMDs) please refer to SOP 51.004.

2. Purpose

The purpose of this SOP is to describe the process for assessing risk of non-CTIMP research studies sponsored or co-sponsored by NHSGGC. The aim is to ensure that potential risks are identified, assessed and mitigated.

The Risk Assessment for Research Studies form (Form 51.043A) is used to determine risk to participants involved in the study. Each study will be assigned a risk category of low, medium or high and may be subject to additional sponsor oversight through risk-proportionate audit or monitoring.

3. Procedures

3.1. Procedure for Risk Assessing a Research Study

The Risk Assessment process is an ongoing activity through the lifecycle of a study; the process of identifying and mitigating risks may begin from the moment NHSGGC are made aware of a study e.g. at grant application stage in relation to resources required, and when developing study documents. However, the formal risk assessment using the Risk Assessment for Research Studies form (Form 51.043A) is undertaken when a reasonably complete version of the protocol becomes available (other study documents can also be reviewed if available) and before the submission of the study to a Research Ethics Committee (REC) so that possible mitigations can be addressed before submission.

As a study risk assessment is a living document, it will undergo further review throughout the study lifecycle e.g. when changes to the protocol are proposed, protocol deviations, serious breaches or new information becoming available that impacts on the study.

Form 51.043A is completed by the Sponsor Research Co-ordinator (SRC), Innovation Sponsor Co-ordinator (ISC) or Sponsor Research Facilitator (SRF).

3.1.1. High Complexity Co-Sponsored Non-CTIMPs

In the event a Co-Sponsored trial has a high degree of complexity, for example in the event of a large number of locations, consideration should be given to completing a risk assessment in line with the CTIMP process, SOP 51.004. This process is intended to classify the perceived risk of a study, whereas the CTIMP process is aimed at detailing and developing mitigations for the risks which is required for more complex studies. This should be discussed on a study by study basis.

3.2. Scoring

The SRC/SIC/SRF will assign a score of between 0-3 to each section of the risk assessment in accordance with the decision trees provided.

Section A	Study Type
Section B	Medicine/Device Used
Section C	Protocol
Section D	Study Support

A total score of 0-4 categorises the study as low risk and a total score of 5-8 categorises the study as medium risk. Both low risk and medium risk studies will not be subject to further risk mitigation strategies unless cause arises. A total score of 9-12 categorises the study as high risk.

Escalation to governance is required where any of the following apply:

- The study is categorised as high risk based on the overall score
- A score of 3 assigned to two or more of the categories (irrespective of total score)
- A safety concern is identified at any point during the study

In these cases, the SRC/SIC/RF will escalate to the Research Governance Manager (RGM) and the RGM will document any mitigation strategies on page 1 of the risk assessment document which may include further oversight e.g. monitoring (in which case the RGM will liaise with the LCTM). The SRC/SIC/SRF will also ensure that safety reporting has been described in the study protocol e.g. any interventional trials should be discussed with the PV Manager.

3.3. Authorisation & Filing

When the Risk Assessment for Research Studies form is complete, it will be authorised by the SRC/SIC/RF and if escalation to governance is required, also authorised by the RGM. Where authorisation by the RGM is required, the completed document will be provided, by the SRC/IC/RF, to the RGM and the document may be more widely circulated at the discretion of the RGM. The authorised the Risk Assessment for Research Studies form will then be filed in the Sponsor e-File as per SOP 51.042. The Senior Research Administrator (SRA) will update SReDA accordingly.

3.4. Updates to the Risk Assessment

Throughout the lifecycle of the study, it may be necessary to re-assess the level of risk e.g. when modifications to the study need to be made in response to a series of non-compliances, a serious breach, or new information impacting the study becoming available.

When a substantial modification to the study is required, the process outlined in SOP 51.021 will be followed. As part of this process, the risk assessment will be reviewed and, if needed, will be updated. This will be documented by creating a new version of Form 51.043A. Each updated version will be clearly version-controlled (e.g. V1, V2, V3, etc.) and populated and reviewed as described above for the original risk assessment.

As per original risk assessment, the form will be deemed to be complete by the SRC/ISC/SRF and authorised as per Section 3.3 of this SOP.

The authorised updated Risk Assessment form will then be filed in the Sponsor e-File, and the previous version moved to a designated 'superseded' folder, as per SOP 51.042.

4. Referenced documents

- SOP 51.004: Risk Assessment for CTIMPs
- Form 51.043A: Risk Assessment for Research Studies form
- SOP 51.021: Review and Approval of Modifications for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow
- SOP 51.042: Preparation and Maintenance of a Non-CTIMP Sponsor e-File

5. Related documents

- SOP 51.041: Sponsor Green Light for non-CTIMPs

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	22/10/2026	First Release	No

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