

Joint Research Management Office Standard Operating Procedure for:

Risk Assessment

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Authorship:		Signature and Date	
Author:	Nadia Rahman, GCP & Governance Manager	Nadia Rahman	Digitally signed by Nadia Rahman Date: 2026.04.24 12:58:11 +01'00'
Reviewer:	Rebecca Newton, Senior GCP and Compliance Manager	Rebecca Newton	Digitally signed by Rebecca Newton Date: 2026.04.27 09:14:07 +01'00'

Authorisation:		Signature and Date	
Name/Position:	Mays Jawad, Associate Director of Research Quality	Dr Mays Jawad	Digitally signed by Dr Mays Jawad Date: 2026.04.27 11:46:41 +01'00'

Purpose:

To standardise the process of carrying out risk assessments (RA) for clinical research studies as part of the Joint Research Management Office (JRMO) decision to sponsor studies.

Scope:

This Standard Operating Procedure (SOP) applies to JRMO staff, especially the Governance Section, and to Bart's Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary) sponsored studies only. This SOP does not apply to externally sponsored, and Queen Mary Research Ethics Committees reviewed studies.

The RA is the responsibility of the sponsor. The local assessment of risks and feasibility will be the responsibility of the local Principal Investigator and Department Review Group (see [SOP 14 Peer Review](#)).

Abbreviations:

Barts Health	Barts Health NHS Trust
CI	Coordinating Investigator
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
Queen Mary	Queen Mary University of London
RA	Risk Assessment
RMGO	Research Management & Governance Officer
SOG	Sponsor Oversight group
SOP	Standard Operating Procedures

SOP Text:		
	Responsibility	Activity
Sponsored Medicines and Healthcare products Regulatory Agency-regulated studies		
1.	Coordinating Investigator (CI)/ Study group/GCP and Governance Manager	Sponsored Medicines and Healthcare products Regulatory Agency (MHRA)-regulated studies will be risk assessed by the CI and study group with support from the Good Clinical Practice (GCP) team. RA should be undertaken as early as possible in the study design stage. It is good practice to undertake RA as a team so everyone is aware of all the potential hazards at each stage of the study and define actions which may be taken. Definitions of the risk categories can be found in Associated Document 1 JRMO Comprehensive Risk Assessment Tool for Sponsored MHRA regulated studies. The completed draft RA form should be submitted with a valid sponsorship submission pack.(SOP 11a Associated Document 3 JRMO document submission checklist for MHRA Regulated Studies and SOP 9 Associated Document 4 JRMO document submission checklist for Clinical Investigations and MHRA regulated Medical Devices). At the sponsorship with conditions stage, a full assessment is performed, and risk adaptations must be incorporated into the protocol and study design using the JRMO Comprehensive RA Tool (Associated Document 1). A copy of the RA must be filed within the sponsor oversight files.
2.	GCP and Governance Manager	As part of sponsorship review the GCP and Governance Manager must review and complete the RA to classify the risk outcome before issuing Sponsorship with Conditions. If there are any medicinal products or pharmacy involvement, the RA must be reviewed by the sponsor pharmacist for relevant input and will also be required to sign the RA. Once the RA has been performed, a risk category will be allocated. It is the risk assessor's discretion to increase the risk rating if it is felt that certain risk areas are heavily weighted and of concern. Action where possible should be taken to lower the risk of these studies through mitigations strategies. If a study is rated as an "unacceptable risk" this should be flagged immediately to the CI and the Senior GCP and Compliance Manager who will work together to lower the risks and hazards to an acceptable level.
3.	GCP and Governance Manager	Feedback and discuss RA with CI/study team. The RA will be discussed and classification agreed.
4.	Research Management Governance Officer (RMGO)/Research Governance Specialist	Log and file completed RA. On receipt of completed RA documentation, log result within EDGE and file document as per SOP 27: JRMO Internal Filing.

5.	GCP and Governance Manager	The RA form should be reviewed and amended if necessary. The GCP and Governance Manager should consider whether the RA is affected when substantial modifications are made to the protocol or other key study documents and document their decision. according to SOP 17a and SOP 17c. The RA should also be considered annually within the JRMO at time of DSUR review. The review is documented in the DSUR workflow. Any updates to the RA should be documented in the RA modification log (Template 1).
Sponsored Interventional Studies		
6.	Assigned RMGO	All Queen Mary and Barts Health Sponsored Interventional and Research Studies will be risk assessed by the allocated RMGO Once all documents have been reviewed within the submission and prior to Sponsorship with Conditions being issued, the assigned RMGO should complete the appropriate RA Tool (Interventional studies, See <i>Associated Documents 2 Interventional Risk Assessment Tool</i>). As part of the RA the RMGO must contact the Quality Assurance Manager and Clinical Research Auditor for a summary of CI non-compliance history and audit outcomes. Once the RA has been performed, a category will be assigned on the basis of the scores allocated. It is the risk assessor's discretion to increase the risk rating if it is felt that certain risk areas are heavily weighted and of concern. All "Moderate" risk studies should be discussed with the Research Governance & Performance Manager. "High" risk studies should also be discussed with the GCP and Governance Manager and Research Governance and Performance Manager and escalated to the Associate Director of Research Quality where needed. The assigned RMGO and Senior RMGO will work with the CI to lower the risks and hazards to an acceptable level. If a study is rated as an "unacceptable risk" this should be flagged immediately to the CI and the Associate Director of Research Quality. The Research Governance & Performance Manager will work with the CI to lower the risks and hazards to an acceptable level.
7.	Assigned RMGO	Once completed, electronically sign the RA form and file as per SOP 27 JRMO Internal Filing. Update EGDE with the RA score.
8.	Assigned RMGO	The RA form should be reviewed and amended if necessary. The assigned RMGO should consider whether the RA is affected when substantial modifications are made to the protocol or other key study documents. If reassessment is needed it will be documented within EDGE. See SOP 17a Amendments for sponsored studies - process for JRMO and SOP 17c Amendments for sponsored studies - process for researchers for further details. The Risk Assessment Modification Tool is to be completed when an RA is to be updated (See Template 1)

Sponsored Research Studies		
9.	Assigned RMGO	Assess if study requires a risk assessment Low risk studies of this type will not require a full risk assessment. See Associated Document 3 Triaging for Research Study Risk Assessment for further details. If a full risk assessment is needed the RMGO is required to follow steps 6 to 8, using <i>Associated Document 2 Interventional Risk Assessment Tool</i>.
All studies		
10.	Sponsor Oversight Group (SOG)	The SOG should be kept up to date with pertinent adaptations / mitigations agreed and should be alerted if the risk level cannot be lowered. If the risk remains unacceptably high at initial RA or following a modification, the SOG will be informed and course of action taken.

Change control

This section outlines changes from version 10.0 to version 11.0

Section changed	Summary and description of changes
Throughout	General administrative changes
Throughout	Update to terminology in line with ICH E6 R3
Associated Document 1	Restructuring and re-writing of the sections related to type A, B, C studies, changed to notifiable v non-notifiable.
Template 1	Implementation of a risk assessment modification tool

List of associated documents

Document ref.	Document name
Associated Document 1	JRMO MHRA regulated Comprehensive Risk Assessment Tool
Associated Document 2	JRMO Interventional Studies Risk Assessment Tool
Associated Document 3	Triaging for Research Study Risk Assessment

List of templates

Document ref.	Document name
Template 1	Risk Assessment Modification Log