Joint Research Management Office Standard Operating Procedure for:			
Risk Assessment			
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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	Chief 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
RM & GO	Research Management & Governance Officer
SOG	Sponsor Oversight group
SOP	Standard Operating Procedures

SOP Text:		
	Responsibility	**Activity**
		Sponsored MHRA-regulated studies
1.	Chief Investigator (CI)/ Study group/GCP and Governance Manager	**Sponsored MHRA-regulated studies will be risk assessed by the CI and study group with support from the GCP team using SOP 23: Associated Document 1 – JRMO Comprehensive RA Tool.** RA should be undertaken as early as possible in the study design stage to identify potential hazards. 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 and be found in Appendix 1. At the sponsorship with conditions stage, a full assessment is performed, and risk adaptions are 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 the CI draft and conduct the RA using the MHRA-regulated tool and classify the RA outcome prior to Sponsorship with Conditions being issued**. 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 score will be allocated on the basis of the number of “High Risk” categories. 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 Research Governance Operations Manager. The GCP and Governance Manager will work with the CI to lower the risks and hazards to an acceptable level.
3.	GCP and Governance Manager	**Feedback and discuss RA with CI.** The RA will be discussed and classification agreed. Once documentation is finalised, email the final documents to the assigned Research Management & Governance Officer (RM & GO).
4.	RM & GO	**Log and file completed RA.** On receipt of completed RA documentation, log result within EDGE and file document electronically, 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 amendments are made to the protocol or other key study documents. If reassessment is needed it will be documented within EGDE. See SOP 17a and SOP 17c for further details.

		The RA should also be considered annually within the JRMO at time of DSUR review. The review is documented in the DSUR workflow.
		Sponsored Research Studies
6.	Assigned RM & GO	**Assess if study requires a risk assessment** Low risk studies of this type will not require a full risk assessment. The EDGE workflow must be used to assess and document if the study does or does not need a full risk assessment (See Associated Document 2 for details). If a full risk assessment is needed the RM & GO is required to follow steps 6 to 8, using Associated Document 3.
7.	Senior RM & GO	Review the EDGE workflow prior to sponsorship being issued to ensure a RA is completed where appropriate.
		Sponsored Interventional Studies
6.	Assigned RM & GO	**All Queen Mary and Barts Health Sponsored Interventional and Research Studies (As per section 6) will be risk assessed by the allocated RM & GO** This includes retrospectively collected data studies and tissue banks where sponsorship is issued. Once all documents have been reviewed within the submission and prior to Sponsorship with Conditions being issued, the assigned RM & GO should complete the appropriate RA Tool (Interventional studies or research studies, See Associated Documents 3). As part of the RA the RM & GO 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 Research Governance Operations Manager where needed. The assigned RM & GO and Senior RM & GO 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 Research Governance Operations Manager. The Research Governance & Performance Manager will work with the CI to lower the risks and hazards to an acceptable level.
7.	Assigned RM & GO	**Once completed, electronically sign the RA form and file as per SOP 27 JRMO Internal Filing.** Update EGDE with the RA score.
8.	Assigned RM & GO	**The RA form should be reviewed and amended if necessary.** The assigned RM & GO should consider whether the RA is affected when substantial amendments are made to the protocol or other key study documents.

		If reassessment is needed it will be documented within EDGE. See SOP 17a and SOP 17c for further details.
All studies		
9.	Sponsor Oversight Group (SOG)	**The SOG should be kept up-to-date with 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 an amendment, the SOG will formally meet with the CI and decide on a course of action.

Change control

This section outlines changes from version to version

Section changed	Summary and description of changes
Section 6	New procedure to assess the requirements of a risk assessment for sponsored research studies
Associated Document 2	New Triaging for Research Study Risk Assessment document
Associated Document 3	Merger of the sponsored research and interventional studies risk assessment tool
All	General administrative changes throughout

List of appendices

Document ref.	Document name
Appendix 1	Definitions of risk categories

List of associated documents

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

Appendix 1:

Low risk: The risk to the participant is no greater than standard care. The procedures and proposals for this study are unlikely to lead to harm to the participant, research group or organisation.

Moderate risk : The risk to the participants is in-line with or greater than standard care. Further risks have been identified however sufficient mitigation is in place to reduce impact to the participant, research group or the organisation.

High risk: Risks have been identified which may significantly affect the safety of the participant, the study integrity, research group or the organisation. Mitigation plans were not able to mitigate to reduce these risks.

Unacceptable risk: The processes and procedures breach requirements of Good Clinical Practice (GCP)/ International Organization for Standardisation 141155, General Data Protection Regulation, Medicines and Healthcare products Regulatory Agency (MHRA) and United Kingdom (UK) regulations where applicable. The study would not conform to sponsor requirement and would be a clear risk to participants, research groups and the organisation