

Joint Research Management Office Standard Operating Procedure for:

Modifications for sponsored studies (including halting studies) - Process for JRMO

SOP Number:	17a	Version Number:	11.0
Effective Date:	18 th May 2026	Review Date:	18 th May 2029

Authorship:		Signature and Date:
Author:	Safia Ornelas Research Governance Specialist	Safia Ornelas Digitally signed by Safia Ornelas Date: 2026.05.01 13:43:27 +01'00'
Reviewer:	Sarah Webb, Research Governance & Performance Manager	Sarah Webb Digitally signed by Sarah Webb Date: 2026.05.01 14:16:44 +01'00'

Authorisation:		Signature & Date:
Name/Position:	Mays Jawad, Associate Director of Research Quality	Dr Mays Jawad Digitally signed by Dr Mays Jawad Date: 2026.05.01 14:57:19 +01'00'

Purpose:

To outline the Joint Research Management Office (JRMO) procedure for processing modifications for studies sponsored by Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary) for all study types.

To ensure that the JRMO maintain oversight of all Barts Health/Queen Mary sponsored study's modifications and give sponsor authorisation prior to the modification being submitted to the applicable regulatory bodies.

To ensure that the most up to date version of documents are stored in the sponsor oversight files and sponsor's local portfolio management system (EDGE).

Scope:

This Standard Operating Procedure (SOP) applies to all studies sponsored by Barts Health/Queen Mary. It applies to all modifications including temporary halting and early termination of research.

For modifications of externally sponsored studies hosted at Barts Health refer to [SOP 17b: modifications for hosted studies](#).

For the process of submitting modifications to the JRMO refer to [SOP 17c: modifications for sponsored studies \(Process for researchers\)](#).

Abbreviations:

Barts Health	Barts Health NHS Trust
CI	Coordinating Investigator
GCP	Good Clinical Practice
HRA	Health Research Authority
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
Queen Mary	Queen Mary University of London

REC	Research Ethics Committee
RMGO	Research Management Governance Officer
RTB	Research Tissue Bank
RGS	Research Governance Specialist
SOP	Standard Operating Procedure

SOP Text:		
	Responsibility	Activity
1.	Research Management and Governance Officer (RMGO)	Allocate modification and check whether the submission is valid. Once the modification document set has been received, including the Modification Log then record the modification on the modification's spreadsheet, and allocate to the RMGO. Allocated RMGO should review the modification submission to confirm if it is valid or invalid. Use following Health Research Authority (HRA) guidance link - The approvals process for modifications (amendments) - Health Research Authority. Template 1, section A can be used to guide researchers.
2.	RMGO	Save the modification documents and update EDGE. Save all the documents under indemnity and EDGE modifications folder, with the folder name labelled appropriately as per SOP 27 JRMO Internal Filing Process. EDGE files, workflow and indemnity files must be kept live throughout the review of the modification. All modifications for Medicines and Healthcare products Regulatory Agency (MHRA) regulated studies must be notified to the Good Clinical Practice (GCP) & Governance Managers to review and approve the modification. A substantial modifications to high risk Interventional or Research studies must be flagged to the Research Governance and Performance Manager. If the modification involves the change of the objectives or endpoints, obtain approval from Trial Steering Committee or Clinical Director. For Research Tissue Banks (RTB), use the modification form as per IRAS guidance. For Queen Mary Research Ethics Committee dual-reviews or retrospective data studies that were not submitted to HRA/ Research Ethics Committee (REC), use modification tool for record purposes but it does not require regulatory submission unless modification involves NHS activity.
3.	RMGO	RMGO to advise researcher on which support department to liaise with i.e., Costing and Contracts, post award team and GCP and Governance Manager as applicable to study type. Obtain support department approvals If the modification involves support departments, obtain approval to proceed:

		- Pathology - Imaging/radiation - Pharmacy - Clinical physics - Lung function - Ophthalmology - Information governance - Point of Care Testing Early contact with support department teams is recommended to prevent delays. If there are any cost implications on the confirmation of cost form, or extension to study, alert the Costing and Contracts team and Post Award teams for review. Request review from the GCP and Compliance team for all modifications related to MHRA regulated studies or if the modification includes the addition of medicines, ingestible products or medical devices. Additions of new eSystems or updates to current eSystems must be supported by new/ updated validation documentation as per SOP 38b Electronic data management systems for MHRA-regulated studies. Any new/ updated eSystem must not go live until full modification review and approval has been completed. If a modification is due to audit/ non-compliance, please liaise with Auditor/ Quality Assurance Manager, as applicable.
4.	RMGO/GCP and Governance Manager	The review of all substantial modifications must include consideration of the modification's effect on the studies original risk assessment. Where the substantial modification affects the study protocol, key study documents or eSystems, consider if a review of the risk assessment is required. The decision to reassess risk or not should be documented clearly in the EDGE workflow.
5.	Costing & Contracts Team	Review cost implications of the modification. Review documentation by assessing any implications on original costing, funding available and need for additional contracts or modifications to contracts. After any cost review, the costing officer should respond to the RMGO with approval or actions required.
6.	GCP Manager & Research Governance Specialist RGS	MHRA regulated studies only - review modification. Governance team review is the lead/main review. The allocated GCP Manager and RGS/RMGO will review all modifications together. (see Associated Document 1 Sponsored amendments guidance for the JRMO). The GCP Manager should provide feedback to RGS/RMGO and confirm that review is completed, complete EDGE GCP workflow and comment if the modification can be approved. If a modification will add the use of new vendor or eSystem, ensure that the research team are aware of the applicable SOPs and the requirement of eSystem validation documentation and potential vendor assessment.

7.	RMGO	Provide feedback RMGO should email the feedback to the Coordinating Investigator (CI) and delegate, with all recommended changes and request they liaise with support departments for approvals, if required. For MHRA regulated studies, the RGS/RMGO and GCP Manager should combine feedback which the RGS/RMGO should collate and send to the CI/delegate.
8.	RMGO/RGS	Arrange authorisation of the modification form. Once the modification review is complete and all queries have been addressed, arrange authorisation of the modification form and authorise on combined review IRAS portal if required for MHRA regulated studies. mailto:research.amendments@qmul.ac.uk For substantial modifications (all routes and conditions) and modifications of an important detail If after submission of the modification, the regulatory bodies request changes to documents, the revised documents must be reviewed by Governance/GCP and Compliance team, as applicable. For minor modifications For this modification type, RMGO/RGS reviews modification and once complete, the modification tool can be locked and modification implemented. These minor modifications are to be communicated to ethics via the next substantial modification for the study. A cover letter listing all previous minor modifications and an outline of what each modification entailed should be clear within the letter. Ensure all final documents are saved to indemnity and EDGE as per SOP 27 Internal Filing Process. Complete workflow on EDGE.
9.	GCP & Governance Manager/RMGO	Raise any issues in line with the JRMO escalation policy. If alerted to a problem with a modification, escalate to Research Governance and Performance Manager or Senior GCP and Compliance Manager. Further escalation may be required to the Associate Director of Research Quality and then the Sponsor Oversight Group where necessary.
10.	RMGO	Check that the JRMO have received all final versions of approved documents. Upon receipt of the review body approvals, ensure that the JRMO are in receipt of all documents including: • Final modification tool or form (e.g. RTB form) • HRA, REC, CAG and MHRA approval letters (where applicable) and all correspondence. • HRA Confirmation of Modification Assessment and all correspondence (Note: Where REC Approval is also required, continuing HRA Approval is conditional on Favourable REC Opinion) • All modified documents as listed on REC approval letter • Final protocol signed by the CI (and statistician for MHRA-regulated studies) if changes were required

11.		For substantial modifications (all routes and conditions) and modifications of an important detail: Issue a modification acknowledgment email using Template 1 Section D which must be sent to the CI copying in the research team and research.amendments@qmul.ac.uk For minor modifications: Issue an modification acknowledgment email using Template 1 Section E which must be sent to the CI copying in the research team and research.amendments@qmul.ac.uk Ensure all final documents are saved (for every modification) to indemnity and EDGE as per SOP27. Complete workflow on EDGE. For MHRA regulated studies, also copy in the GCP & Governance Manager and allocated Clinical Trial Monitor.
12.	JRMO Clinical Trial Monitor/Clinical Trials Facilitator	Save MHRA-regulated modification documents and correspondence in the sponsor file. Ensure updated versions of study documents are filed in Indemnity and appropriate sponsor oversight file as per SOP 27 Internal Filing Process.
Special Amendments		
13.	GCP & Governance Manager or RMGO	Manage Urgent Safety Measures Upon notification of an urgent safety measure from the CI, request the details of the hazard and the full justification for the urgent safety measure. Ensure that the CI has contacted the REC and, where relevant, MHRA Clinical Trials Unit and, where required, seek advice from a Clinical Director of R&D. Once an urgent safety measure has been implemented, ensure that the CI notifies the REC and, where relevant, MHRA in writing within 7 days. Request the written notification and review it for accuracy and completeness. Ensure that the CI submits a substantial modification to document the urgent safety measure 7 days. Review the modification as a priority and notify the modifications team that the modification should be treated as a priority.
14.	RMGO or GCP & Governance Manager	Manage halted studies. If the sponsor or CI decides to halt the study temporarily, remind the CI of their responsibility to notify the REC (and MHRA for MHRA-regulated studies) immediately and at the latest within 15-days from when the study is temporarily halted. This should take the form of a substantial modification. The notification must clearly explain what has been halted (for example, stopping recruitment and/or interrupting treatment of subjects already included) and the reasons for the temporary halt. A temporary halt is defined as a stoppage of either the study or one or more research sites not foreseen in the protocol, but with the intent to resume the study in the future. To restart a study that has been temporarily halted via a modification, another modification must be submitted.

		If the study is not restarted, an early termination should be submitted as per <i>JRMO SOP 18a Study Closure Sponsored MHRA-regulated studies</i> or <i>SOP 18b Study closure for sponsored interventional and research studies and all hosted studies</i>. Once an End of Trial has been submitted, further modifications cannot be made.
--	--	---

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
Throughout	Update to process for modification classification in line with ICH E6 R3

Associated documents

Document Reference	Document name
Associated Document 1	Sponsored modifications guidance for the JRMO

Template documents

Document Reference	Document name
Template 1	Modification guidance and template emails