

Joint Research Management Office Standard Operating Procedure for:

Modifications for hosted studies

SOP Number:	17b	Version Number:	8.0
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Authorship:		Signature and Date:
Author:	Safia Ornelas, Research Governance Specialist	Safia Ornelas Digitally signed by Safia Ornelas Date: 2026.05.01 13:38:54 +01'00'
Reviewer:	Sarah Webb, Research Governance & Performance Manager	Sarah Webb Digitally signed by Sarah Webb Date: 2026.05.01 14:17:16 +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 14:57:49 +01'00'

Purpose:	
To set out the requirements for the review and approval of amendments to research studies hosted at Barts Health NHS Trust (Barts Health) and/or Queen Mary University of London (Queen Mary), prior to their implementation. To ensure that researchers are aware of the relevant requirements for gaining approvals from the Medicine & Healthcare products Regulatory Agency (MHRA), Health Research Authority (HRA) and Research Ethics Committee before implementing any modifications for research studies that are hosted at Barts Health NHS Trust or Queen Mary University of London. To outline the Joint Research Management Office (JRMO) procedure for processing modifications to studies which have been granted final approval/confirmation of capacity and capability (C&C) by the JRMO.	
Scope:	
This standard operating procedure (SOP) applies to all studies hosted by Barts Health and Queen Mary. For studies sponsored by Barts Health and Queen Mary refer to SOP 17a: Modifications for sponsored studies (for JRMO) and SOP 17c: Modifications for sponsored studies (for researchers).	
Abbreviations:	
Barts Health	Barts Health NHS Trust
CECM	Centre for Experimental Cancer Medicine
HRA	Health Research Authority
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
Queen Mary	Queen Mary University of London
RMGO	Research Management Governance Officer
SOP	Standard Operating Procedure

SOP Text:		
Substantial modifications, modifications of important details, and modifications of minor details		
	Responsibility	Activity
1.	Local Investigator /research team/sponsor	Send modification pack to JRMO Sponsor sends modification notification pack, together with a locked modification tool, and confirmation of implementation date to the generic email address: research.amendments@qmul.ac.uk.
2.	RMGO (Research Management Governance Officer)	Acknowledge and review modification Acknowledge receipt of the modification to the sponsor/sponsor's representative and assess the impact of the modification. Query any unclear impacts with the sponsor/local research team for any potential modification implications to site. Add the modification to the central spreadsheet completing all required data fields. For information on what the modification pack should include, please see Associated Document 1 JRMO Hosted Modifications Guidance Document • Request any missing documents that the sponsor may not have sent across. • Save all documents and correspondence in the relevant investigator's study folder within the Indemnity folder on the shared drive and EDGE as per SOP27 Internal Filing Process • If longer than the 35-day implementation date is required to review the modification, then the reviewer will need to raise an objection/notify the sponsor.
3.	RMGO	Request Support Department approvals If the modification has an impact on support departments, please request each affected department to review and issue their approval for the modification. Please see the Associated Document 1 JRMO Hosted Modification Guidance Document to find contact details of relevant support departments. Costing and contracts implication should be brought to the attention of the Pre-award Costings and Contracts team Forward to the costings and contract team. Save the email, draft costing spreadsheet and contract addendum in the relevant modification folder within indemnity.
4.	Pre-award costing and contracts team	Review modification Review cost and contracts implications, obtain approval from study team for cost change, amend any contracts as necessary and get sign off. For Commercially sponsored studies, where there are any new changes to costs and contract associated with the modification, the Sponsor/ Contract Research Organisation should include: 1. A summary of what the modification is changing from the current agreed Clinical Trial Authorisation/Protocol. 2. Draft Costing Spreadsheet with changes to original budget highlighted clearly. 3. Draft Contract Addendum/modification denoting changes made – preferably not just 'financial appendix to be removed and replaced with the contents of this modification'.

5.	RMGO	Finalise modification Complete the respective modification workflow on EDGE, upload documents, correspondence and acknowledgement e-mail under the 'Documents' section on EDGE and update the central spreadsheet to reflect the modification review is complete. Once modification review is complete send an Acknowledgement/Approval email (See Associated Document 1 Hosted Amendment Guidance Document) and send a copy of the agreement to site if the contract has been modified. If there has been a modified protocol / Barts Health Local Investigator change, please copy in any applicable support department as an FYI that provided approval during initial C&C.
6.	Study team	File and implement modification Ensure acknowledgement is received from the JRMO and file all correspondence and document to the investigator site file. Supersede any updated versions of documents.

CANCER STUDY MODIFICATIONS

	Responsibility	Activity
7.	RMGO/Designated person/CECM team	Cancer study modifications are reviewed and approved by the Centre for Experimental Cancer Medicine (CECM) team. Any cancer modifications received in the modifications inbox should be forwarded to the crdgamendments@nhs.net for their review. Once the modification has been reviewed and approved by Cancer Research Delivery Group team, the approval email should be filed and saved in indemnity and EDGE by the RMGO. <u>Paediatric cancer studies</u> For cancer studies that include both adults and children, two approvals will be required: - One for the adult portion of the study (the CECM will only review the documents applicable to the adult study) - One for the paediatric portion of the study (documents applicable to the paediatric portion of the study will be reviewed and approved by the clinical Director).

Change control

This section outlines changes from version 7.0 to 8.0 version

Section changed	Summary and description of changes
Throughout	Terminology update in line with ICH E6 (R3)
Throughout	General administrative changes
Throughout	Update to modification classifications in line with ICH E6 (R3)

List of associated documents

Document list	Document title
Associated Document 1	JRMO Hosted Modifications Guidance Document