

Joint Research Management Office Standard Operating Procedure for:

Amendments for hosted studies

SOP Number:	17b	Version Number:	7.0
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Purpose:	
<p>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 (REC) approval(s) before implementing any amendments for research studies that are hosted at Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary).</p> <p>To outline the Joint Research Management Office (JRMO) procedure for processing amendments to studies which have been granted final approval/confirmation of capacity and capability by the JRMO.</p>	

Scope:	
<p>This standard operating procedure (SOP) applies to all studies hosted by Barts Health and Queen Mary.</p> <p>For studies sponsored by Barts Health and Queen Mary refer to <i>SOP 17a: Amendments for sponsored studies (for JRMO)</i> and <i>SOP 17c: Amendments for sponsored studies (for researchers)</i>.</p>	

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
REC	Research Ethics Committee
RMGO	Research Management Governance Officer
SOP	Standard Operating Procedure

SOP Text:		
Substantial and Non-Substantial Amendments		
	Responsibility	Activity
1.	Principal Investigator (PI)/research team/sponsor	<p>Send amendment Pack to JRMO</p> <p>Sponsor sends amendment notification pack, together with a locked amendment tool, and confirmation of implementation date to the generic email address: research.amendments@qmul.ac.uk.</p>
2.	RMGO	<p>Acknowledge and Review amendment</p> <p>Acknowledge receipt of the amendment to the sponsor/sponsor's representative and assess the impact of the amendment. Query any unclear impacts with the sponsor/local research team for any potential amendment implications to site.</p> <p>Add the amendment to the central spreadsheet completing all required data fields. For information on what the amendment pack should include, please see Associated Document 1 JRMO Hosted Amendments Guidance Document</p> <ul style="list-style-type: none"> • 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 amendment, then the reviewer will need to raise an objection/notify the sponsor.
3.	RMGO	<p>Request Support Department approvals</p> <p>If the amendment has an impact on support departments, please request each affected department to review and issue their approval for the amendment. Please see the Associated Document 1 JRMO Hosted Amendment Guidance Document to find contact details of relevant support departments.</p> <p>Costing and contracts implication should be brought to the attention of the Pre-award Costings and Contracts team</p> <p>Forward to the costings and contract team. Save the email, draft costing spreadsheet and contract addendum in the relevant amendment folder within indemnity.</p>
4.	Pre-award costing and contracts team	<p>Review amendment</p> <p>Review cost and contracts implications, obtain approval from study team for cost change, amend any contracts as necessary and get sign off.</p> <p>For Commercially sponsored studies, where there are any new changes to costs and contract associated with the amendment, the Sponsor/ Contract Research Organization should include:</p> <ol style="list-style-type: none"> 1. A summary of what the amendment is changing from the current agreed Clinical Trial Authorisation. 2. Draft Costing Spreadsheet with changes to original budget highlighted clearly. 3. Draft Contract Addendum/Amendment denoting changes made – preferably not just 'financial appendix to be removed and replaced with the contents of this amendment'.

5.	RMGO	<p>Finalise amendment</p> <p>Complete the respective amendment workflow on EDGE, upload documents, correspondence and acknowledgement e-mail under the 'Documents' section on EDGE and update the central spreadsheet to reflect the amendment review is complete.</p> <p>Once amendment 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 amended. If there has been an amended protocol / Barts Health PI change, please copy in any applicable support department as an FYI that provided approval during initial C&C.</p>
6.	Study team	<p>File and implement amendment</p> <p>Ensure acknowledgement is received from the JRMO and file all correspondence and document to the investigator site file. Supersede any updated versions of documents.</p>

CANCER STUDY AMENDMENTS

	Responsibility	Activity
	RMGO/Designated person/CECM team	<p>Cancer study amendments are reviewed and approved by the Centre for Experimental Cancer Medicine (CECM) team.</p> <p>Any cancer amendments received in the amendment inbox should be forwarded to the crdgamendments@nhs.net for their review.</p> <p>Once amendment 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.</p> <p><u>Paediatric cancer studies</u></p> <p>For cancer studies that include both adults and children, two approvals will be required:</p> <ul style="list-style-type: none"> - 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 6.0 to 7.0 version

Section changed	Summary and description of changes
All	Administrative changes throughout
Responsibilities	Change of job title
Associated Document 1	New guidance document
Template 1	Email Templates

List of associated documents

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

List of Templates

Document list	Document title
Template 1	JRMO Hosted Amendments Email Templates