Joint Research Management Office Standard Operating Procedure for:			
Amendments for hosted studies			
SOP Number:	**17b**	Version Number:	**V6.0**
Effective Date:	**10th June 2022**	Review Date:	**10th June 2025**

Authorship & Review:			
Author:	**Tumi Kaminskas, Research Governance and Performance Manager**		
Signature:	*The signed original is held within the JRMO office*	**Date**	
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Signature:	*The signed original is held within the JRMO office*	**Date:**	
Reviewer:	**Ginette Hoare, Interim Research Governance Operations Manager**		
Signature:	*The signed original is held within the JRMO office*	**Date:**	

Authorisation:			
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Signature:	*The signed original is held within the JRMO office*	**Date:**	

Purpose:

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).

To outline the Joint Research Management Office (JRMO) procedure for processing amendments to studies which have been granted final R&D approval/confirmation of capacity and capability 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: Amendments for sponsored studies (for JRMO)* and *SOP 17c: Amendments for sponsored studies (for researchers)*.

Abbreviations:

AA	Amendments Administrator
AO	Amendments Officer
Barts Health	Barts Health NHS Trust
CECM	Centre for Experimental Cancer Medicine
CRO	Contract Research Organization
GCP	Good Clinical Practice
HRA	Health Research Authority
ISF	Investigator Site File
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
RM	Research Management
SOP	Standard Operating Procedure

Definitions:

- Local portfolio management system: Is a research management system, which is used to monitor and report on research activity within Barts Health.

Relevant SOPs:

• SOP 10	Confirmation of capacity and capability
• SOP 17a	Amendments for sponsored studies (Process for JRMO)
• SOP 17c	Amendments for sponsored studies (Process for researchers)

SOP Text:

Substantial and Non-Substantial Amendments

	Responsibility	Activity
1.	Principal Investigator (PI)I/research team/sponsor	**Send amendment Pack to JRMO** 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
2.	Amendments Administrator (AA)/Amendments Officer(AO)/Designated person	**Acknowledge and Review amendment** **A**cknowledge receipt of the amendment to the sponsor/sponsor's representative and query with the sponsor any potential amendment implications to site. Add the amendment to the central spreadsheet completing all required data fields. Note implementation date. • The document pack for the amendment should include: o PDF version of the amendment tool o REC Favourable Opinion letter(if required for the amendment)

		○ HRA approval email (if required for the amendment) ○ MHRA approval letter (if applicable) ○ HRA correspondence confirming no regulatory approvals required (This is for specific amendments only- if applicable) ○ Final Approved document set by regulators • Request any missing documents that the sponsor may not have sent across. • Save all documents in the relevant investigator's study folder within the Indemnity folder on the shared drive • If longer that the 35-day implementation date is required to review the amendment, then the reviewer will need to raise an objection/notify the sponsor.
3.	AA/AO/Designated person/Pre-award team	**Request Support Department approvals** **Any 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 amendment folder within indemnity. • Update the central amendment spreadsheet in the shared drive. **If applicable, obtain Imaging/Pathology/Pharmacy/Clinical Physics approval.** If the amendment has an impact on support departments, please request each affected department to review and issue their approval for the amendment. Please send the request to the imaging team on the following email address: imgingrsrchamendment.bartshealth@nhs.net Please send the request to the pathology team on the following email address: bartshealth.ResearchPathology@nhs.net Please send the request to the pharmacy team on the following email address: Ctpharmacy.bartshealth@nhs.net Please send the request to the Clinical Physics team on the following email address: research.clinicalphysics@nhs.net
4.	Pre-award costing and contracts team	**Review amendment** Review cost and contracts implications, seek clarification where required, amend any contracts and get sign off. For Commercially sponsored studies, where there are any new changes to costs and contract associated with the amendment,

		the Sponsor/ Contract Research Organization (CRO) should include: 1. Provide summary of what the amendment is changing from the current agreed CTA. 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.	AA/AO/Designated person	**Finalise amendment** Complete the respected amendment workflow on EDGE and update the central spreadsheet to reflect the amendment review is complete. Once amendment review is complete a "No objection to the amendment" (use Appendix 1 Email template) and agreement for site to implement the amendment will be issued.
6.	Study team	**File and implement amendment** Ensure acknowledgement is received in the JRMO and file all correspondence and document to the investigator site file. Supersede any updated versions of documents.
CANCER STUDY AMENDMENTS		
	Responsibility	**Activity**
	AA/AO/Designated person/CECM team	**Cancer study amendments are reviewed and approved by the Centre for Experimental Cancer Medicine (CECM) team.** The amendment reviewer should receive notification of amendment from the CECM team from the following email address: CRDGamendments@nhs.net. **The amendment reviewer will then complete the following checks:** 1. Check all documents and approvals have been uploaded to the CRDG Amendment folder on EDGE by the CRDG Amendments team 2. If all in place then issue R&D Acknowledgement email 3. Complete JRMO review of CRDG Amendment workflow on EDGE 4. Upload the R&D Acknowledgement email to the CRDG Amendment folder

		Paediatric cancer studies CECM will not review and approve amendments for paediatric cancer studies; these will be completed by obtaining appropriate Clinical Department Authorisation. For cancer studies that include both adults and children 2 approvals will be required: - 1 for the adult portion of the study (the CECM will only review the documents applicable to the adult study) - 1 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). The JRMO amendment reviewer must then: • Ensure all support department approvals are in place • Ensure costing and contracts approval (if applicable) is in place • File documents in Indemnity • Update and save documents to EDGE • Update the Amendment Tracker • Send email receipt to CECM team • Complete standard amendment workflow on EDGE

Change control

This section outlines changes from version to version

Section changed	Summary and description of changes
All	Administrative changes throughout

List of appendices

Appendix	Document title
Appendix 1	Email template

List of associated documents

There are no associated documents for this SOP.

Appendix 1

Dear PI,

RE: study title

IRAS ID:

Amendment: SAX DD.MM.2020

REC approval: DD.MM.2020

HRA approval: DD.MM.2020

MHRA approval: DD.MM.2020

Impact

IMAGING: not applicable

PHARMACY: not applicable

PATHOLOGY: not applicable

COSTING/CONTRACT AMENDMENT: not applicable

Documents reviewed: All approved documents as per REC favourable opinion letter dated 7th October 2021

This amendment has been reviewed for Barts Health NHS Trust and can be implemented.

Please contact us using the details below if you require any further information

Kind regards