

SOP 17b Associated Document 1 Hosted Amendments Guidance (For the JRMO)

Queen Mary University of London or Barts Health NHS Trust is the site only.

As per HRA guidance, some amendments can be implemented immediately with no study-wide review required, e.g. no impact on the Barts Health site. The process would be to acknowledge/approval and save documents on file.

Amendments are either Substantial or Non-substantial. They are then further categorized into:

- A.** Implications for, or affects, all participating organisations. This may involve changes to activity or cost implications. - [must be reviewed fully as per process below](#)
- B.** Implications for, or affects, specific participating organisations. This may involve changes to activity or cost implications for these organisations. – [if there is no impact to Barts Health/Queen Mary, then amendment does not require review. Acknowledge receipt of email and save documents on file for record purposes. If it does impact Barts Health/Queen Mary, then review as per process described below](#)
- C.** No implications that require management or oversight by the participating organisations. The amendment is still provided for information. There are no changes to site activity or cost implications. Participating organisations might need to take some action, such as updating contact details. – [The amendment does not need any review unless it has implications; then the review is processed as below.](#)

The amendment pack should include the following:

- PDF version of the amendment tool
- [HRA, REC, MHRA or CAG approval letter](#) - (if applicable for the amendment)
- HRA correspondence confirming no regulatory approvals required (This is for specific amendments only_- if applicable)
- Final Approved document set by regulators

JRMO Amendment Process

1. Receive notification of hosted amendment, either the full amendment package with all documents and approvals or notification of the amendment with all documents before approvals are issued. Check on EDGE (red site level) if the C&C has been issued, and the date the site confirmed has been filled. Then, process the amendment as below. If the C&C is not issued, the RMGO reviewing the C&C should process the amendment as pre-C&C.
2. Create an amendment folder using the Sponsor amendment reference number provided in the amendment tool under the PI's study folder on the Shared Drive and EDGE. Save the amendment notification email and all associated documents.

3. Initiate the EDGE amendment workflow on the red level as per the EDGE manual - (ensure it is updated live throughout the amendment review according to the EDGE manual).
4. Acknowledge the receipt of the amendment and inquire with the sponsor/research team if there is an impact on support departments (see template email 1 below). If not already provided, request the relevant regulatory approvals (All required approvals can be found at the bottom of the amendment tool).
5. If the amendment impacts the recruitment target or study extension dates, inquire with the study team/sponsor about any changes to the local recruitment target. If yes, please copy in the Pre-award team if this affects the initial funding agreement.
6. If there is an impact on support departments, email the amendment pack to the relevant team. Copy the research team and wait for approval before proceeding, leaving a comment as "pending" and specify which department within the support department on EDGE (in the workflow).
 - Pharmacy approval from
 - Generic pharmacy - ctpharmacy.bartshealth@nhs.net
 - Royal London specific- rlhpharmacyct.bartshealth@nhs.net
 - St Bartholomew's specific - clinicaltrials.bartshealth@nhs.net
 - Ophthalmology - anu.sharma5@nhs.net
 - Clinical physics - research.clinicalphysics@nhs.net
 - Medical photography (if patient face will be used) - darrin.hawkins@nhs.net
 - Pathology (if local lab) - bartshealth.researchpathology@nhs.net
 - POCT - pointofcaretrlh.bartshealth@nhs.net
 - Cardiac Imaging - bartshealth.cardiacresearchdiagnostics@nhs.net
 - Imaging - bartshealth.researchimaging@nhs.net
 - Lung Function - andrew.eaton1@nhs.net, nolan.stain1@nhs.net
 - Costing and contracts - jrmo-bartshealth@qmul.ac.uk
7. If you have the regulatory approvals, cross-check version and dates mentioned within the REC approval match the study documents received. If not, liaise with the sponsor to obtain any missing documentation. Once you have all support department approvals, regulatory approvals, and necessary documents, issue the approval email (Approval email template provided below). The acknowledgment email should be addressed to the PI and copied to the study team, sponsor, relevant support department/s, and the generic amendment inbox.
 - 7.1. If the amendment has a Barts Health Principal Investigator (PI) change or the study end date, copy in sss.crnorththames@nihr.ac.uk in the acknowledgment email. Obtain the CV-GCP of the new PI.
8. Complete the EDGE workflow and update the red level in case of PI/recruitment target/study or recruitment end date changes. Upload documents to EDGE and Shared Drive.
9. Update the Amendment tracker once the amendment has been acknowledged/approved.