

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

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

As per HRA guidance, some modifications 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.

Modifications are categorized in the following manner for MHRA regulated studies only:

Substantial modifications

- i) Route A
- ii) Route B
 - i) Condition A
 - ii) Condition B
 - iii) Condition C

Modifications of an important detail

Minor modifications

For non-MHRA regulated studies the categories are:

Substantial Modification

Substantial Modification of Important Detail

Minor Modification

The modification pack should include the following:

- PDF version of the modification tool
- HRA, REC, MHRA and/or CAG approval letter - (if applicable for the modification)
- IRAS outcome email confirming no regulatory approvals required (this is for specific modifications only_- if applicable)
- Final Approved document set by regulators

JRMO Modification Process

1. Receive notification of hosted modification, either the full modification package with all documents and approvals or notification of the modification 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 modification as below. If the C&C is not issued, the RMGO reviewing the C&C should process the modification as pre-C&C.
2. Create a modification folder using the Sponsor modification reference number provided in the modification tool under the PI's study folder on the Shared Drive and EDGE. Save the modification notification email and all associated documents.

3. Initiate the EDGE modification workflow on the red level as per the EDGE manual - (ensure it is updated live throughout the modification review according to the EDGE manual).
4. Acknowledge the receipt of the modification 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 modification tool).
5. If the modification 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 modification 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) or advise research team of all relevant support department approvals needed and request for the approvals to be forwarded once obtained.
 - Pharmacy approval from
 - Generic pharmacy - ctpharmacy.bartshealth@nhs.net
 - Royal London specific- rlhpharmacyst.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 - jrm-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 local Investigator and copied to the study team, sponsor, relevant support department/s, and the generic modifications inbox.

7.1. If the modification has a Barts Health local Investigator change or the study end date, copy in nl.rrdn@nihr.ac.uk in the acknowledgment email. Obtain the CV-GCP of the new Investigator.
8. Complete the EDGE workflow and update the red level in case of Investigator/recruitment target/study or recruitment end date changes. Upload documents to EDGE and Shared Drive.
9. Update the Modification tracker once the modification has been acknowledged/approved.