| Joint Research Management Office Standard Operating Procedure for: | | | |
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| **Amendments for sponsored studies (including halting studies) - Process for JRMO** | | | |
| SOP Number: | **17a** | Version Number: | **10.0** |
| Effective Date: | **2nd January 2025** | Review Date: | **2nd January 2028** |

| **Authorship:** | | **Signature and Date:** |
|---|---|---|
| Author: | Safia Ornelas,<br>Senior Research Management and Governance Officer | Safia Ornelas Digitally signed by Safia Ornelas Date: 2024.12.20 12:49:55 Z |
| Reviewer: | Sarah Webb,<br>Research Governance & Performance Manager | Sarah Webb Digitally signed by Sarah Webb Date: 2024.12.23 12:27:56 Z |

| **Authorisation:** | | **Signature & Date:** |
|---|---|---|
| Name/Position: | Mays Jawad,<br>Research Governance Operations Manager | Dr Mays Jawad Digitally signed by Dr Mays Jawad Date: 2024.12.23 12:46:05 Z |

## Purpose:

To outline the Joint Research Management Office (JRMO) procedure for processing amendments for studies sponsored by Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary).

To ensure that the JRMO are aware of all Barts Health/Queen Mary sponsored studies amendments and give sponsor authorisation prior to the amendment being submitted to the applicable regulatory bodies.

To ensure that the most up to date version of documents are stored in the sponsor oversight files and sponsor's research database application (EDGE).

## Scope:

This Standard Operating Procedure (SOP) applies to all studies sponsored by Barts Health/Queen Mary. It applies to all amendments including temporary halting and early termination of research.

For amendments of externally sponsored studies hosted at Barts Health refer to SOP 17b: Amendments for hosted studies.

For the process of submitting amendments to the JRMO refer to SOP 17c: Amendments for sponsored studies (Process for researchers).

## Abbreviations:

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| Barts Health | Barts Health NHS Trust |
| CI | Chief Investigator |
| GCP | Good Clinical Practice |
| HRA | Health Research Authority |
| JRMO | Joint Research Management Office |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| QMERC | Queen Mary Ethics of Research Committee |

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| Queen Mary | Queen Mary University of London |
| REC | Research Ethics Committee |
| RMGO | Research Management Governance Officer |
| RTB | Research Tissue Bank |
| SOP | Standard Operating Procedure |

| **SOP Text:** | | |
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| | **Responsibility** | **Activity** |
| **1.** | Research Management and Governance Officer (RMGO) | **Allocate amendment and check whether the submission is valid.**<br><br>Once the amendment document set has been received, record the amendment on the amendment's spreadsheet, and allocate to the RMGO.<br><br>Allocated RMGO should review the amendment submission to confirm if it is valid or invalid and whether substantial or non-substantial. RMGO to respond to the email from the Chief Investigator (CI)/study team within five working days, confirming validation of the amendment or if invalid, to request further documents/information.<br><br>Template 1, section A can be used to guide researchers. |
| **2.** | RMGO | **Save the amendment documents and update EDGE.**<br><br>Save all the documents under indemnity and EDGE amendments folder, with the folder name labelled appropriately as per SOP 27 JRMO Internal Filing Process:<br>• Type: Substantial or non-substantial<br>• Reference: Sub Am number i.e. SA5<br><br>EDGE files, workflow and indemnity files must be kept live throughout the review of the amendment.<br><br>All amendments for Medicines and Healthcare products Regulatory Agency (MHRA) regulated studies must be notified to the Good Clinical Practice (GCP) & Governance Managers to review and approve the amendment.<br><br>All high risk Interventional and Research studies must be flagged to the Research Governance and Performance Manager.<br><br>If the amendment involves the change of the objectives or endpoints, obtain approval from Trial Steering Committee or Clinical Director.<br><br>For Research Tissue Banks (RTB), use the amendment form as per IRAS guidance. For Queen Mary Ethics of Research Committee (QMERC) dual-reviews or retrospective data studies that were not submitted to Health Research Authority (HRA)/Research Ethics Committee (REC), use amendment tool for record purposes but it does not require regulatory submission unless amendment involves NHS activity. |
| **3.** | RMGO | **RMGO to advise researcher on which support department to liaise with i.e., Costing and Contracts, post award team and GCP and Governance Manager as applicable to study type.**<br><br>**Obtain support department approvals** |

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| | | If the amendment involves support departments, obtain approval to proceed:<br>- Pathology<br>- Imaging/radiation<br>- Pharmacy<br>- Clinical physics<br>- Lung function<br>- Ophthalmology<br>- Information governance<br>- Point of Care Testing<br><br>Early contact with support department teams is recommended to prevent delays.<br><br>If there are any cost implications on the confirmation of cost form, or extension to study alert the Costing and Contracts team and Post Award teams for review.<br><br>Request review from the GCP and Compliance team for all amendments related to MHRA regulated studies or high-risk Interventional studies being monitored by the GCP and Compliance team or if the amendment includes the addition of medicines, ingestible products and medical devices.<br><br>Additions of new eSystems or updates to current eSystems must be supported by new/updated validation documentation as per SOP 38b Electronic data management systems for MHRA-regulated studies. Any new/updated eSystem must not go live until full amendment review and approval has been completed.<br><br>If an amendment is due to audit/non-compliance, please liaise with Auditor/Quality Assurance Manager, as applicable.<br><br>Liaise with QMERC team for any amendments of dual review with QMERC studies |
| **4.** | RMGO/GCP and Governance Manager | **The review of all substantial amendments must include consideration of the amendments effect on the studies original risk assessment.**<br><br>Where the substantial amendment affects the study protocol, key study documents or eSystems, consider if a full review of the risk assessment is required. The decision to reassess risk or not should be documented clearly in the EDGE workflow. |
| **5.** | Costing & Contracts Team | **Review cost implications of the amendment.**<br><br>Review documentation by assessing any implications on original costing, funding available and need for additional contracts or amendments to contracts.<br><br>After any cost review, the costing officer should respond to the RMGO with approval or actions required. |
| **6.** | GCP & Governance Manager | **MHRA regulated studies only - Review amendment.**<br><br>Governance team review is the lead/main review. The allocated GCP and Governance Manager will review all substantial amendments and selected non substantial amendments (see Associated Document 1 Sponsored amendments guidance for the JRMO). |

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| | | The GCP and Governance Manager should provide feedback to RMGO and confirm that review is completed, complete EDGE workflow and comment if the amendment can be approved.<br><br>If an amendment will add the use of new vendor or eSystem, ensure that the research team are aware of the applicable SOPs and the requirement of eSystem validation documentation and potential vendor assessment. |
| **7.** | RMGO | **Provide feedback**<br><br>RMGO should email the feedback to the CI and delegate, with all recommended changes and request they liaise with support departments for approvals, if required.<br><br>For MHRA regulated studies, the RMGO and GCP and Governance Manager should combine feedback which the RMGO should collate and send to the CI/delegate. |
| **8.** | RMGO | **Arrange authorisation of the amendment form.**<br><br>Once the amendment review is complete and all queries have been addressed, arrange authorisation of the amendment form and authorise on combined review IRAS portal if required.<br><br>Once the form is complete and signed, send email using (Template 1 Section 2 ) copying in the CI, research team and research.amendments@gmul.ac.uk.<br><br>**For substantial; category A,B,C and non-substantial notifiable; category A, B, C**<br><br>If after submission of amendment, the regulatory bodies request changes to documents, the revised documents must be reviewed by Governance/GCP and Compliance team, as applicable.<br><br>**For non-substantial non-notifiable; category C**<br><br>For this amendment type, the review is now complete, and amendment can be implemented<br><br>Ensure all final documents are saved to indemnity and EDGE as per SOP 27 Internal Filing Process. Complete workflow on EDGE. |
| **9.** | GCP & Governance Manager/RMGO | **Raise any issues in line with the JRMO escalation policy.**<br><br>If alerted to a problem with an amendment, escalate to Research Governance and Performance Manager or Senior GCP and Compliance Manager. Further escalation may be required to the Research Governance Operations Manager and then the Sponsor Oversight Group where necessary. |
| **10.** | RMGO | **Check that the JRMO have received all final versions of approved documents.**<br><br>Upon receipt of the review body approvals, ensure that the JRMO are in receipt of all documents including:<br><br>• Final Amendment tool or form (e.g. RTB form) |

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| | | • HRA, REC and MHRA approval letters (where applicable) and all correspondence.<br>• HRA Confirmation of Amendment Assessment and all correspondence (Note: Where REC Approval is also required, continuing HRA Approval is conditional on Favourable REC Opinion)<br>• All amended documents as listed on approval letters<br>• Final protocol signed by the CI (and statistician for MHRA-regulated studies) if changes were required<br><br>**For substantial; category A, B, C:**<br>Issue an amendment acknowledgment email using Template 1 Section D which must be sent to the CI copying in the research team and research.amendments@qmul.ac.uk<br><br>**For non-substantial notifiable; category A, B, C:**<br>Issue an amendment acknowledgment email using Template 1 Section E which must be sent to the CI copying in the research team and research.amendments@qmul.ac.uk<br><br>Ensure all final documents are saved to indemnity and EDGE as per SOP27. Complete workflow on EDGE.<br><br>For MHRA regulated studies, also copy in the GCP & Governance Manager and allocated Clinical Trial Monitor. |
| | RMGO | **Notify Study Support Service and Performance team** |
| **11.** | JRMO Clinical Trial Monitor/Clinical Trials Facilitator | **Save MHRA-regulated amendment documents and correspondence in the sponsor file.**<br>Ensure updated versions of study documents are filed in Indemnity and appropriate sponsor oversight file as per SOP 27 Internal Filing Process. |
| | | **Special Amendments** |
| **12.** | GCP & Governance Manager or RMGO | **Manage Urgent Safety Measures**<br>Upon notification of an urgent safety measure from the CI, request the details of the hazard and the full justification for the urgent safety measure. Ensure that the CI has contacted the REC or MHRA Clinical Trials Unit and, where required, seek advice from the Clinical Director of R&D.<br>Once an urgent safety measure has been implemented, ensure that the CI notifies the REC and MHRA in writing within 3 days. Request the written notification and review it for accuracy and completeness.<br>Ensure that the CI submits a substantial amendment to document the urgent safety measure within two weeks. Review the amendment as a priority and notify the amendments team that the amendment should be treated as a priority. |
| **13.** | RMGO or GCP & Governance Manager | **Manage halted studies.**<br><br>If the sponsor or CI decides to halt the study temporarily, remind the CI of their responsibility to notify the REC (and MHRA for MHRA-regulated studies) **immediately and at the latest within 15-days from when the study is temporarily halted.** This should take the form of a substantial amendment. |

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| | | The notification must clearly explain what has been halted (for example, stopping recruitment and/or interrupting treatment of subjects already included) and the reasons for the temporary halt. A temporary halt is defined as a stoppage of either the study or one or more research sites not foreseen in the protocol, but with the intent to resume the study in the future.<br><br>To restart a study that has been temporarily halted via an amendment, another amendment must be submitted.<br><br>If the study is not restarted, an early termination should be submitted as per JRMO SOP 18a Study Closure Sponsored MHRA-regulated studies or SOP 18b Study closure for sponsored interventional and research studies and all hosted studies. Once an End of Trial has been submitted, further amendments cannot be made. |

## Change control

This section outlines changes from version 9.0 to version 10.0

| Section changed | Summary and description of changes |
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| Responsibilities | Change of job title |
| Throughout | Inclusion of consideration to e-system changes |
| Section 4 | Consideration to update risk assessment |
| Associated Document 1 | New guidance document |
| Template 1 | Email Templates |

## Associated documents

| Document Reference | Document name |
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| Associated Document 1 | Sponsored amendments guidance for the JRMO |

## Template documents

| Document Reference | Document name |
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| Template 1 | Amendment guidance and template emails |