

Joint Research Management Office Standard Operating Procedure for:

Study closure for sponsored MHRA-regulated studies

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Purpose:

This standard operating procedure (SOP) outlines the responsibilities and processes for the closure of Medicines and Healthcare products Regulatory Agency (MHRA) regulated research studies sponsored by Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary). It describes the actions required to ensure that (i) regulatory close out notifications are submitted to the appropriate regulatory bodies and (ii) study closure is formally completed within the Joint Research Management Office (JRMO) systems and records.

Scope:

This SOP applies to Barts Health and Queen Mary sponsored studies regulated by the MHRA, including clinical trials of investigational medicinal products (CTIMPs), advanced therapy investigational medicinal products (ATIMPs) and clinical investigations of medical devices.

This SOP does not apply to non-MHRA regulated studies or hosted studies- For all those studies, please see [JRMO SOP 18b Study closure for sponsored interventional, research studies and Hosted studies](#).

Abbreviations:

ATIMP	Advanced Therapy Investigational Medicinal Product
Barts Health	Barts Health NHS Trust
CAG	Confidentiality Advisory Group
CI	Coordinating Investigator
CSR	Clinical Study Report
CTIMP	Clinical Trial of an Investigational Medicinal Product
EoT	End of Trial
GCP	Good Clinical Practice
HRA	Health Research Authority
IRAS	Integrated Research Application System
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
Queen Mary	Queen Mary, University of London
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TMF	Trial Master File

SOP Text:		
	Responsibility	Activity
1.	Coordinating Investigator (CI)	During the study, inform the JRMO promptly of any changes that might affect the study's end date/definition. This includes changes that impact: • When the funding will run out, • Research Ethics Committee (REC) or MHRA approved duration, • The duration the study is active at locations (as per location confirmation or agreements). <u>Any changes to the end of trial (EoT) definition constitutes a modification and <i>SOP 17c Modifications for sponsored studies</i> should be followed.</u> Extensions to study timelines must be discussed and agreed with the relevant Good Clinical Practice (GCP) and Governance manager prior to implementation.
2.	CI	Assess whether the study has met the EoT definition defined in the protocol and ensure that all study activities are completed within the approved timeframe. Once the EoT definition is reached, the CI has a maximum of 90 calendar days to submit the appropriate EoT. <u>Once EoT/study notifications are submitted, no further study activity can occur with the study participants, no modifications can be submitted and no new data or samples may be collected.</u> Early termination. Where a study is terminated early (i.e. before the EoT definition has been reached, as defined in the protocol), the EoT form must be submitted within 15 days, and clear reasons should be given for early termination and details of any follow-up measures required for safety reasons, where applicable. Early termination does not include studies that complete earlier than the planned timelines because full recruitment has been achieved. Early termination of a study may occur due to reasons other than safety concerns, such as financial or business considerations or persistent recruitment issues. In such cases the CI should contact the JRMO GCP & Governance Manager to discuss their plans prior to submission.
3.	CI / Delegate	Email a copy of the EoT form downloaded from Combined Review system or Health Research Authority (HRA) website together with any covering letters to research.governance@qmul.ac.uk. For all studies operating under Confidentiality Advisory Group (CAG approval), draft email to CAG as per latest HRA guidance. In the email to the JRMO, the CI must confirm that:

		• EoT definition has been met (with separate written confirmation from the statistician if different from the CI). • Status of laboratory work and sample storage. • Location close out visits have been scheduled. • When the statistical analysis will be completed. • Anticipated date for submitting Clinical Summary Report (CSR) (this must be within 12 months of the EoT). Please allow a minimum of one working week for the GCP team to review the submitted documentation.
4.	JRMO GCP and Governance Team	Begin the appropriate study closure workflow in EDGE. Once the review is complete, authorise submission of the documents.
5.	CI / Delegate	Once GCP team authorisation is received, submit EoT form and send copy of submission and acknowledgements to the JRMO. Where IRAS Combined Review is not in use, the “Declaration of End of Trial form” should be submitted to both the MHRA and REC simultaneously. For clinical investigations of medical devices, the “Declaration of the end of a study” form should be submitted to the REC, and a letter confirming the end of the study should be submitted to the MHRA. File a copy of the EoT form in the trial master file (TMF), along with all correspondence and associated documentation.
6.	CI	Notify all locations, laboratories, and relevant facilities of study closure. Where local location activity has ended prior to EoT these locations may be closed at any time. The CI must provide each location’s local Investigator with the study closure procedure and ensure close-out visits are completed in accordance with the Monitoring Plan and preparation for Archiving (25 years for CTIMPs/ clinical investigations or 30 years for ATIMPs, see SOP 20 Archiving Transferring research study records to Corporate Records). The location of all documentation must be communicated to the coordinating team. All study data should be fully collected and cleaned, and any database lock formally documented. Laboratories must follow the protocol, with samples either transferred to an HTA-registered tissue bank or destroyed within 12 months of EoT. For further information please email Katie Ersapah, Designated Individual and HTRC Manager; k.ersapah@qmul.ac.uk. Other vendors must be formally notified of closure and provided with close-down procedures/archiving instructions.

7.	CI	Write a Final Report. For CTIMPs, ATIMPs, and Clinical Investigations, the CI must prepare a final CSR within 12 months of EoT. The CSR must include: • CTIMPs and ATIMPs: statement of compliance with GCP and list any deviations to protocol and GCP. • Clinical Investigations of Medical Device: statement of compliance with ISO 14155 and list any deviations to the protocol and ISO 14155. Send a PDF draft of the final report to the JRMO GCP & Governance Manager at least three weeks before submission deadline. Once reviewed by JRMO, submit as per HRA website guidance and send final copy/acknowledgements to JRMO as well as filing in the TMF. A lay summary of the study results must be provided to participants (and relevant people, e.g. their carers or parents) and uploaded to the study's public registry within 12 months of study end (6 months for paediatric studies, extendable to 12 months with an objective scientific justification). For blinded studies, participants must be informed of their treatment allocation once the study blind has been lifted. Log into the public database website and enter the details of final report.
8.	JRMO GCP Team	Process final report. Once final copy of report received: • Complete workflow (including date draft received, submission and acknowledgement details) There may be a sponsor requirement to include a pre-agreed statement relating to potential study conduct and/or data integrity. On receipt of any publication/final report for review, the JRMO GCP team will review the EDGE CSR workflow to identify the need for such statements and ensure these are added to the documentation.
9.	JRMO GCP Team	Ensure that EDGE is updated accordingly. The GCP team must update site level to closed (of any kind) when notified local Barts Health sites are closed. The GCP Team, at EOT, update project level to Closed – Follow up complete, followed by Completed once the CSR is received. Enter the EoT date as the date on the EoT form. Determine the date that the CSR is due (one year from the EoT) and enter a reminder in ReDA. Complete the EDGE workflow previously started.

10.	CI	Notify all other required parties of the study's closure (e.g. funder, public database) and archive your study. Ensure that all contractual reporting obligations have been fulfilled. Include details of what information was required and when it was reported, e.g. safety reports & study milestones. Organise research files e.g., TMF to ensure all necessary documents are present and retained. Archive study files following SOP 20 Archiving Transferring research study records to Corporate Records. Discuss archiving electronic data with Corporate Records Manager and the JRMO if applicable. JRMO should be informed that archiving has occurred and of archiving details.
11.	CI	Publication. Please see JRMO policy https://www.jrmo.org.uk/ (for overarching policy) The sponsor (Barts Health or Queen Mary) must be acknowledged on all publications resulting from a Queen Mary or Barts Health sponsored study. All publications must comply with sponsor and regulatory requirements, funder and collaborator publication agreements and terms. In the event that research misconduct or data integrity concerns have been raised, the JRMO, as sponsor along with the senior management of the affected organisation, reserves the right to review, request a hold on publication submission, or refuse permission to publish in discussion.

Change control

This section outlines changes from version 7.0 to version 8.0.

Section changed	Summary and description of changes
Section 7	Mandated requirement to provide participants a lay report of study results
Throughout	Update to terminology in line with ICH E6 R3
Throughout	General administrative changes

List of appendices

None

List of associated documents

None