Joint Research Management Office Standard Operating Procedure for:			
Study closure for sponsored interventional & research studies and all hosted studies.			
SOP Number:	**18b**	Version Number:	**5.0**
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Purpose:

To outline the process that researchers must follow when a Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) sponsored research study or an externally sponsored research study (i.e., study that is not sponsored by Barts Health or Queen Mary) has been completed.

To ensure that the appropriate regulatory bodies have been notified and that the study is also closed in the Joint Research Management Office (JRMO) and archived appropriately.

Scope:

This Standard Operating Procedure (SOP) covers procedures for research teams and JRMO staff working on:

- Barts Health and Queen Mary sponsored studies which are not regulated by the Medicines and Healthcare products Regulatory Agency (MHRA)
- Externally sponsored research studies of all types

For clinical trials of investigational medicinal products (CTIMPS), advanced therapy investigational medicinal products (ATIMPS) or clinical investigations of medical devices, please see *JRMO SOP 18a Study Closure for sponsored MHRA-regulated studies*.

Abbreviations:

ATIMP	Advanced Therapy Investigational Medicinal Product

Barts Health	Barts Health NHS Trust
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
EoT	End of Trial
GCP	Good Clinical Practice
HRA	Health Research Authority
HTA	Human Tissue Authority
IRAS	Integrated Research Application System
ISF	Investigator Site File
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
NIHR	National Institute for Health Research
PI	Principal Investigator
Queen Mary	Queen Mary, University of London
QMS	Quality Management System
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TMF	Trial Master File
UKCRN	UK Clinical Research Network

Definitions:

For Hosted studies and for the purpose of this SOP the End of trial (EoT) is reached at the site is when the sponsor confirms in writing that they now consider the site closed *(this may be when the EoT is reached, or any other time point when the sponsor confirms that the study is closed).*

Relevant SOPs:

• SOP 17c	Amendments for sponsored studies (including halting studies) - Process for researchers
• SOP 18a	Study closure for MHRA-regulated studies (Process for researchers)
• SOP 20	Archiving (transferring research projects to corporate records management)
• SOP 40	Vendor assessment

SOP Text:

Sponsored Interventional and Research studies only

	Responsibility	Activity
1.	Chief Investigator (CI)	**During the study, inform the JRMO if there are any changes to the study that may impact upon when it is due to end.** For example, if there is any change during the study that will impact upon: • When the funding will run out • Research Ethics Committee (REC) approved duration

		• The duration the study is active at sites (as per site confirmation or agreements). Any changes to the EoT definition is a substantial amendment and *SOP 17c Amendments for sponsored studies* should be followed. Extensions to study timelines are non-substantial amendments, but these must be discussed and agreed with the JRMO.
2.	CI	**Assess whether the study has met the EoT definition and ensure that all study activity is completed within the appropriate timeframe.** The CI must maintain oversight of the progress of the study and identify when the study has "ended", per the EoT definition in the protocol. Once the EoT definition is reached, the CI has a maximum of 90 calendar days to ensure all aspects of the study have been completed and submit the Declaration of the end of a trial form. For example, all data must be collected and cleaned. "Database Lock" must have occurred and be documented. Laboratory work must have been performed as per protocol and samples appropriately transferred to a Human Tissue Authority (HTA) registered tissue bank or destroyed. *Once the EoT notification is submitted,* ***no further activity can occur*** *with the study participants, no amendments can be submitted, no new data or samples collected, and no queries can be issued.*
3.	CI/Delegate	**Notify the JRMO of the end of the study.** The following documents must be completed and emailed to research.governance@qmul.ac.uk: • Declaration of the end of a trial form (available on the HRA website) • Confirmation that if Barts Health is a site, that the EDGE entry is correct and up to date. • For All Studies working under Confidentiality Advisory Group (CAG approval) Draft email to CAG as per latest HRA guidance. • Covering letter to REC (if applicable) Please allow **one working week** for the JRMO to review the EoT form.
4.	JRMO Governance Administrator or delegated other	**Review the EoT documentation.** Begin the appropriate study closure workflow in EDGE. Review the end of trial form and associated documents for accuracy and completeness. Confirm that: • The end of trial definition has been met. • There are no open audits of the study (liaise with JRMO auditor). • There are no open non-compliances in the sponsor's record (liaise with the JRMO Quality Assurance (QA) Manager). • The study record is up to date on EDGE. • Forward closure notification to jrmo-helpdesk-smdpostaward@qmul.ac.uk Once the review is complete, authorise submission of the documents.

5.	CI/Delegate	**Submit EoT form to REC or HRA.** Once approved by the JRMO, the CI must submit a final copy of the "Declaration of the end of a trial form" and associated documents. If the study has been approved by a REC, the notification should be submitted to the REC. For studies that are exempt from REC review, the notification should be submitted to the HRA. Please refer to the HRA website for up-to-date information on how and where to send the form. The CI must then send a copy of the final signed version of the EoT form to the JRMO along with acknowledgments of receipt from the REC or HRA. CI must save a copy in the end of trial form in the trial master file (TMF), along with all correspondence and associated documentation.
6.	CI	**Early termination.** Where a study is terminated early (i.e., before the EoT definition has been reached, as defined in the protocol), the declaration of the end of a trial form must be submitted to REC or HRA within 15 days. As with other study closures, the documents specified in section 3 of this procedure must first be submitted to research.governance@qmul.ac.uk for review. Where a study is terminated early, the *declaration of the end of the study* form must specify the reason(s) for the early termination. The *declaration of the end of the study* or cover letter should also describe any activities that must be completed to complete the study e.g., additional follow-up of participants for safety reasons, data cleaning, sample analysis etc. These additional activities must have clear timelines for completion. 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 be due to reasons other than safety concerns, such as financial or business difficulties of the sponsor or related to slow recruitment.
7.	JRMO Governance Administrator or delegated other	**Update EDGE and the Indemnity folder.** Ensure that the green project level study status is updated to " completed". Enter the EoT date as the date on the end of trial form.
8.	CI (Central Facilities) Principal Investigator (PI) (Site level) / Delegate	**Inform support departments of the EoT.** All support departments involved in the study must be informed that the study has closed. Support departments will follow their own procedures to close the study – this is usually done separately to the study team.
9.	CI	**Notify sites, laboratories, and facilities of study's closure.** All sites must be sent a copy of the EoT form and any REC or HRA acknowledgements. The CI must provide all site PIs with the study's closure procedure. Where close out visits or phone calls have been planned in the study protocol or other essential documents, these must take place.

		Laboratories must be notified, and instructions given for close down procedures. Sites must be given instruction to ensure that all essential study-related material is present and complete for the appropriate length of time: Interventional studies – 25 years Research Studies – 5 years The site must inform the CI and Coordinating Team of the archiving location. This must include the investigator site file (ISF), and any trial-specific files in support departments. (See SOP 20 Archiving)
10.	CI	**Write a Final Report.** Within 12 months of the study ending**,** write a final report for the research study. Every report must include JRMO minimum requirements (See Appendix 1) All reports must state compliance to Good Clinical Practice (GCP) and list any deviations to the protocol and GCP that have occurred. Send the report to the REC, or to the HRA if the study is exempt from REC review. Send a copy to the JRMO via research.governance@qmul.ac.uk. Ensure acknowledgement is received, forward to the JRMO as per above and filed in TMF.
11.	JRMO Governance Administrator or delegated other	**Update EDGE and save documentation.** Complete EDGE closure workflow and file the documentation as per SOP 27 JRMO Internal Filing
12.	CI	**Notify all parties of the study's closure (e.g., funder, public database) and archive the study.** If the research study has been adopted by the National Institute for Health Research (NIHR), upload a lay report to the UK Clinical Research Network (UKCRN) for publication on the NIHR website. Update public databases of results where applicable, i.e., clinicaltrials.gov or similar. If the study protocol / agreement states that participants or other parties will be notified of the study results (e.g., funders or other third parties provided with results of the study), it is the CI's responsibility to send them a copy of the final report or results. 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. For studies involving human tissue, all samples must be analysed and either passed to a licensed tissue bank (with appropriate consent and approvals in place; please refer to Barts Health and Queen Mary Human Tissue and Cell Research policies) or destroyed prior to the final study report being submitted. Organise research files e.g., TMF to ensure all necessary documents are present and retained.

		Archive study files in accordance with *JRMO SOP 20 Archiving*. Discuss archiving electronic data with the Corporate Records Manager and the JRMO if applicable. JRMO should be informed that archiving has occurred and of archiving details.
13.	CI	**Publication.** 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 funder and collaborator publication agreements/terms. In the event that research misconduct or data integrity concerns have been raised, the JRMO 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. A final copy of all publications, abstracts and presentations should be forwarded to the JRMO and filed in the TMF.
Hosted Studies		
14.	PI/Research team	**Inform the JRMO of study closure and file paperwork as appropriate.** The sponsor or sponsor's representative will confirm in writing that the site is now closed and confirm the date of closure. A copy of this email or letter should be filed in the ISF, with a copy sent via research.governance@gmul.ac.uk to the JRMO. As part of this ensure the JRMO is informed of: • Date the site was closed by the sponsor • Confirm that the EDGE records are up to date
15.	JRMO Governance Admin or delegate	**<u>Log study closure</u>** Save notification email and sponsor email in Indemnity and EDGE at red site level. Check EDGE site level status has been changed to closed (as per EDGE manual).

Change control

This section outlines changes from version **4.0** to version **5.0**

Section changed	Summary and description of changes
All	Clarification of processes
All	Merger of SOP 18b and 18c

List of appendices

Appendix 1 Minimum requirements

Appendix 1

Every report must include JRMO minimum as listed below:

- **A.** Statement to clearly state if the study's objectives were met.
- **B.** Description of study population.
- **C.** Results / main findings. This should include data as well as a descriptive conclusion.
- **D.** Safety – including all events.
- **E.** Statement of compliance to the UK Policy Framework for Health and Social care research, GCP and the protocol. This should include any deviations to protocol and GCP that have occurred and the impact of these on the data and general compliance.
- **F.** Arrangements for publication or dissemination of the research, including any feedback to participants.