Queen Mary University of London

NHS Barts Health NHS Trust

Standard Operating Procedure (SOP) for:			
Project Closure: Process for JRMO Staff			
SOP Number:	**19**	Version Number:	**5.0**
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Purpose:

This standard operating procedure (SOP) outlines the process that Joint Research Management Office (JRMO) staff must follow when a Barts Health NHS Trust (BH) or Queen Mary University of London (QMUL) sponsored MHRA-regulated trial has been completed, to ensure that the appropriate regulatory bodies are notified and records are updated before the trial files are archived.

Scope:

This process is mandatory for all sponsored trials regulated by the MHRA: clinical trials of an investigational medicinal product (CTIMPs), advanced therapy investigational medicinal products (ATIMPs) and clinical investigations (e.g. clinical trials of non-CE marked medical devices or medical devices used outside of their CE marking). For all other sponsored projects, please refer to the JRMO guidance document on project closure.

This SOP is applicable to both Governance and Post Award JRMO staff. It describes the actions completed by the JRMO following declaration of the end of the trial; including end of trial notification (EOTN) to the competent authority (CA) and research ethics committee (REC), and end of trial (EOT) close out procedures.

Abbreviations:

AE	Adverse Event
APR	Annual Progress Report
ATIMP	Advanced Therapy Investigational Medicinal Product
CA	Competent Authority
BH	Barts Health NHS Trust

CAPA	Corrective and Preventative Action
CI	Chief Investigator
COV	Close Out Visit
CSO	Clerical Support Officer
CSR	Clinical Study Report
CTIMP	Clinical Trial of an Investigational Medicinal Product
DSUR	Development Safety Update Report
EOT	End Of Trial
EOTN	End Of Trial Notification
GCP	Good Clinical Practice
IMP	Investigational Medicinal Product
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
QMUL	Queen Mary University of London
REC	Research Ethics Committee
ReDA	Research Database Application
SOP	Standard Operating Procedure

Definitions:

- **End of Trial (EOT)**: may be the last visit of the last subject or a later time point. The EOT must be defined in the protocol.

Relevant SOPs:

- SOP 17c - Process for Researchers: Amendments for sponsored studies.
- SOP 18a - Process for Researchers: Project closure: Guidance for research staff of sponsored studies.
- SOP 18b - Project Closure: Guidance for research staff of hosted projects.
- SOP 20 - Transferring Research project records to corporate records management (known as Archiving).
- SOP 28 - Monitoring.

SOP Text

	Responsibility	Activity
1.	GCP & Governance Manager	**Track when regulated trials are due to end.** When the CI has confirmed EOT as defined in the protocol or when a trial ends prematurely, the GCP & Governance Manager will provide guidance to the trial team to ensure that the EOTN is submitted within the required timeframes. As EOT approaches, the following must be considered: • Plans for analysis of the data. • Have all serious breaches been reported to the sponsor and all corrective and preventative actions (CAPAs) been followed up to resolution? • Have all the data queries from monitoring and auditing visits been resolved? Has a monitoring close out visit (COV) been

		• Has the data lock taken place and, if so, has this been documented? • Has all completed and withdrawn participant data been accounted for before analysis and has this been documented? • Was an interim publication written? If so, are there any participants who are still on the trial or in follow-up who might be affected by the publication of trial results? For example, if treatment has been proven effective, the trial participants may wish to be un-blinded. Consider the ethical implications of informing the participants; input from the trial REC may be needed. • Have arrangements been made with pharmacy for the destruction or return of all remaining investigational medicinal product (IMP)? • Have all unused trial supplies been returned or destroyed according to trial requirements? • Have arrangements been made for the destruction or ongoing storage of retained biological samples and diagnostic material? • Update the research database application (ReDA) with minutes of trial committee meetings, annual progress reports (APRs), development safety update reports (DSURs), recruitment numbers, adverse events (AEs) (according to the GCP Checklist), and request other documents and information as necessary.
2.	GCP & Governance Manager	**Acknowledge receipt of the EOTN, authorise the CI to submit the EOTN on behalf of the sponsor, inform the study monitor and update the clinical trials spreadsheet.** Ensure the EOTN is completed fully and request any changes where necessary. When the EOTN is complete, authorise the CI to submit to the relevant CA and REC: • UK-only trials: EOTN must be submitted to the MHRA and REC which issued favourable opinion. • Multinational trials: EOTN must be submitted to the CA and REC in all countries concerned. Ensure the EOTN is submitted within the required timeframes: • 90 days for planned EOT. • 15 days for a trial that ends prematurely. The CI must provide the JRMO with the final signed copy of the EOTN and any acknowledgements from the CA and REC. Inform the appropriate JRMO Trial Monitor of the EOTN. Update the clinical trials spreadsheet.
3.	JRMO monitor	**Remind the CI and trial team of their responsibilities, including the requirement to submit a clinical study report (CSR) and to archive at all sites. Perform a COV, also update ReDA and EDGE database with the EOT date.** Discuss the EOT close out procedures with the trial team to ensure a monitoring COV is performed in accordance with the trial specific monitoring

<table>
<tr><td></td><td></td><td>plan and SOP 28 Monitoring.

Enter the EOT end date, as stated on the EOTN form, into ReDA (see ReDA manual for details). Tick EOTN in the ReDA "Event" tab.

The EOTN, and acknowledgments from REC and CA must be saved in the following:
• ReDA under the "Trial Docs" tab.
• "Indemnity" shared folder.
• JRMO sponsor file.

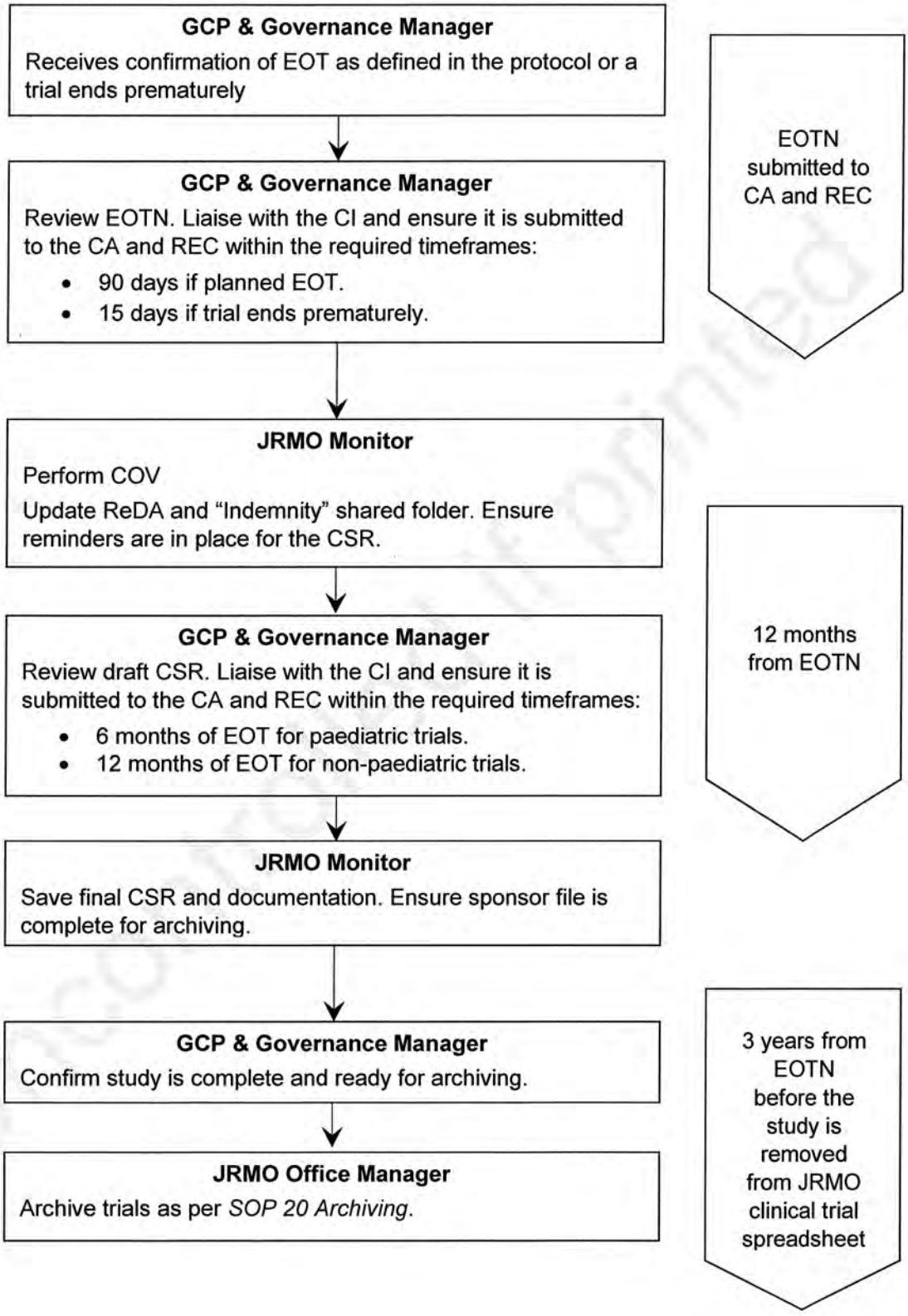
Ensure that ReDA email reminders are set to prompt the CI to submit the CSR within the required timeframes:
• 6 months of EOT for paediatric trials.
• 12 months of EOT for non-paediatric trials.</td></tr>
<tr><td>4.</td><td>GCP & Governance Manager</td><td>Acknowledge and review the CSR.</td></tr>
<tr><td>5.</td><td>JRMO monitor</td><td>File CSR and prepare files for archiving.

Once the CSR is received, save in the following:
• ReDA under the "Trial Docs" tab.
• "Indemnity" shared folder.
• JRMO sponsor file.

Three years after receipt of the EOTN, liaise with the GCP & Governance Manager to confirm that the trial can be archived before passing the sponsor file to the JRMO Office Manager for archiving.</td></tr>
<tr><td>6.</td><td>JRMO Office Manager or delegate</td><td>Inform the GCP & Governance Manager of any MHRA-regulated trials where the finance is closed or is being closed. Archive the trial once notified by the GCP & Governance Manager.
<table>
<tr><th>Post Award Status</th><th>Governance Status</th><th>Status on ReDA</th></tr>
<tr><td>Finance Active</td><td>End of study notification received</td><td>Governance Closed</td></tr>
<tr><td>Finance Closed</td><td>End of study notification not received</td><td>Governance Active</td></tr>
<tr><td>Finance Closed</td><td>End of study notification received and 3 years after EOTN received by the JRMO (when the study is removed from JRMO clinical trial spreadsheet)</td><td>Completed</td></tr>
</table>
For "Governance Closed" studies with active funding, inform the Post Award team so that the finance status can be checked.

Research files should be <u>archived only when the GCP & Governance Manager has confirmed that the study is "Completed"</u>. For archiving procedures see SOP 20 Transferring Research Project Records to Corporate Records Management (known as Archiving).</td></tr>
</table>

End of Trial Flowchart for JRMO staff



Change Control

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

Section Changed	Summary and description of changes
All	Changed parts 1 and 2, and combined into a single process.
All	General administrative changes.

List of Appendices

There are no appendices for this SOP.

List of Associated Documents

There are no associated documents for this SOP.