Standard Operating Procedures (SOP) for:			
Project Closure – Guidance for Research Staff of Hosted Projects			
SOP Number:	**18b**	Version Number:	**3.0**
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Purpose and Objective:
To outline the process that researchers should follow when an externally (not Barts Health NHS Trust or Queen Mary University of London) sponsored research project has been completed.
Scope:
This SOP covers procedures for research teams working on externally sponsored projects only. For the purposes of this SOP, the term 'completed' covers projects where all aspects of the project are completed, including early termination and never started projects. For closures of projects sponsored by either Barts Health NHS Trust or Queen Mary University of London, please see *SOP 18a Process for Researchers: Project Closure for Sponsored Studies*. For the JRMO's internal processes for project closures, please see *SOP 19 Project Closure – Process for JRMO Staff*.

Abbreviations:	
EOT	End of Trial
HRA	Health Research 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 of Health Research
REC	Research Ethics Committee

Definitions *(if needed):*
Relevant SOPs:
SOP 18a Process for Researchers: Project Closure for Sponsored Studies. SOP 19 Project Closure – Process for JRMO Staff SOP 20 - Transferring Research Project Records to Corporate Records Management (known as Archiving)

SOP Text		
	Responsibility	Activity
1.	PI/Research team	**Inform the JRMO of project closure and file paper work as appropriate.** The definition of the end of a project is specified in the research protocol and in IRAS. If the research project has ended early for any reason, follow the same procedures as outlined below. The sponsor or sponsor's representative will provide a copy of the End of Trial Declaration (see HRA and MHRA websites for current form) to REC and MHRA (where applicable). When acknowledgement of receipt has been received, it should be filed together with the declaration form in the Investigator Site File (ISF), with a copy of each to be sent to the Joint Research Management Office (JRMO).
2.	PI/Research team	**As part of the end of study notification, report to the JRMO the following information for projects conducted at BH/QMUL site(s):** • Total number of participants recruited at site • Date the last participant was recruited • Date of the last follow-up visit at site • Date the site was closed by the sponsor See *Associated Document 1: JRMO End of Study Notification Form*
3.	PI/Research team	**Once EOT notifications are submitted, no further activity can occur with the study participants**. No new data may be collected and no queries may be issued. Database Lock should have also occurred. Analysis of samples previously collected can occur. No changes or amendments can be made to the study once EOTs are submitted.
4.	PI/Research team	**Ensure Pharmacy and other service departments are involved if applicable.** If pharmacy was/is involved in the project, they should be notified that the project has closed. Pharmacy will follow their SOP on study closure procedures and archiving, this is usually done separately.
5.	PI/Research team	**Contact sponsor to arrange close out visit.** The sponsor of the study will be expected to conduct a study close out visit (on site or by telephone), and, at a minimum, provide instructions on how to close the site and archive. Organise research files to comply with the sponsor's instructions.
6.	PI/Research team	**File a copy of the final report, and the study lay summary, in the ISF and forward to the JRMO.** A final report for the research project must be written by the sponsor or

		sponsor's representative within one year of the end of trial notification. For more information on the requirements of the report, please see the HRA website. JRMO to acknowledge receipt.
7.	PI/Research team	**Archive project file** Archiving should occur on site and following *SOP 20 - Transferring Research Project Records to Corporate Records Management (known as Archiving).* Discuss archiving electronic data with Modern Records Manager and the JRMO if applicable. Sponsor should be informed of location of archiving.

Change Control

This section outlines changed from version 2.0 to version 3.0.

Section Changed	Summary and description of change
Document	Reformatted/amended to current SOP template format
1	Previous SOP sections 1 and 2 (of v2.0) combined into current section 1. (subsequent sections re-numbered accordingly) "NRES" amended to "HRA"
2	Section and reporting responsibilities added.
4	Amended to include other service departments
6 & 8 (of v2.0)	Sections deleted.
Associated Documents	Addition of mandatory JRMO End of Study Notification Form

Associated Documents

	Document Title:
Associated Document 1	JRMO End of Study Notification Form

The JRMO would like to acknowledge the Centre for Experimental Cancer Medicine for its templates that have been used and incorporated to create this SOP.