Joint Research Management Office Standard Operating Procedure for:

Archiving: Transferring research study records to Corporate Records

SOP Number:	20	Version Number:	7.0
Effective Date:	27th March 2023	Review Date:	27th March 2026

Authorship & Review:		**Signature and Date:**
Author:	Marie-Claire Good Senior GCP and Governance Manager	Marie-Claire Good Digitally signed by Marie-Claire Good Date: 2023.03.02 10:45:21 Z
Reviewer:	Sandra Blake Corporate Records Manager	Sandra Blake Digitally signed by Sandra Blake Date: 2023.03.13 11:15:58 Z

This SOP was also reviewed by Paul Smallcombe, Records & Information Compliance Manager, and Maria Rhodes, Office Manager and PA.

Authorisation:		**Signature & Date:**
Name/Position:	Mays Jawad Research Governance Operations Manager	Dr Mays Jawad Digitally signed by Dr Mays Jawad Date: 2023.03.14 13:24:10 Z

Purpose:

The purpose of this standard operating procedure (SOP) is to provide guidance on the transfer of research study records into an appropriate archive for secure long-term storage at the end of each study.

This is to comply with the UK Policy Framework for health and social care research, the Data Protection legislation and Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary) Policies on the Retention and Disposal of Records (based on NHS Records Management Code of Practice 2021).

Scope:

This SOP applies to all clinical research studies sponsored by and/or hosted within Barts Health and Queen Mary. Steps 1-3 of the procedure only apply to Medicines and Healthcare Regulatory Agency (MHRA)-regulated studies sponsored by Barts Health or Queen Mary. Steps 4 onward apply to all studies.

This SOP does not describe the process of archiving Joint Research Management Office (JRMO) files or the archiving arrangements at external host sites.

Uncontrolled if printed

Abbreviations:	
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
EudraCT	European Union Drug Regulating Authorities Clinical Trials Database
GCP	Good Clinical Practice
ISF	Investigator site file
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare Regulatory Agency
PI	Principal Investigator
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TMF	Trial Master File

SOP Text:		
	Responsibility	**Activity**
1.	Chief Investigator (CI)	**Request permission to archive from the JRMO (Sponsored MHRA-regulated studies only).** Submit a written request to archive to the JRMO Research Governance and Good Clinical Practice (GCP) Manager responsible for the study. Confirm the following in the request: • The Clinical Study Report has been submitted to, and acknowledged by, the MHRA and Health Research Authority (HRA). • Results of the study have been posted to the European Union Drug Regulating Authorities Clinical Trials Database (EudraCT) and/or any other applicable public databases that the study has been registered on. • The Trial Master File (TMF) is complete.
2.	JRMO clinical trial monitor	**When requested by the GCP and Governance Manager check that the JRMO sponsor oversight files are present and complete (sponsored MHRA-regulated studies only).** Confirm that all required paper or electronic records are present, following *SOP 27 JRMO Internal Filing Process*, including but not limited to a copy of the End of Trial Notification, a copy of the Clinical Study Report and acknowledgements from the MHRA and REC. Check that EDGE and REDA has been updated to reflect the status of the study. Request any missing documents from the study team. Once the check is complete, notify the Research Governance and GCP Manager that permission to archive can be issued.

Uncontrolled if printed

3.	Research Governance and GCP Manager	**Issue permission to archive once the above actions are complete (sponsored MHRA-regulated studies only).**
4.	CI/ Principal Investigator (PI) or delegate	**Receive permission to archive.** • Sponsored MHRA-regulated studies may be archived once permission has been received from the Research Governance and GCP Manager (see steps 1 to 3 above). • All other sponsored studies should be archived once the HRA have acknowledged the study's final report. • Hosted studies may be archived once permission has been received from the study sponsor or CI. Clinical study documentation should be archived in a timely manner following permission to archive. Archiving should be completed by the CI/PI or by a member of the research team delegated archiving responsibilities on the study delegation log. When permission to archive is obtained, the CI/PI or delegate should confirm that all essential study-related material is present and complete. This must include the pharmacy file and any study-specific laboratory files. If any documents are filed separately from the main study file, for example centrally stored training records then a file note should be placed in the TMF or Investigator site file (ISF) detailing where the document is stored. For hosted studies, notify the JRMO via research.governance@qmul.ac.uk that permission to archive has been received.
5.	CI/ PI or delegate	**Assess the archiving requirements and identify an appropriate archive.** Both Queen Mary and Barts Health retention policies indicates that research records should be retained as below. The start of the retention period is the date of the end of study notification. The above timelines apply to all documentation irrespective of its type, format and the department that it is located in. This includes, but is not

Type of research	Length of retention
Research falling under remit of the MHRA or international equivalent	25 years
Advanced therapy medicinal products (as defined by the MHRA)	30 years
Interventional studies - Research where the participants' care or treatment is being changed	25 years
Research studies - Any clinical research study where there is no change to the participants' care or treatment, and any nonclinical research study	5 years

Uncontrolled if printed

		limited to Sponsor Files, Contracts, Financial records, TMFs, ISFs, Pharmacy Site Files, laboratory files, laboratory accreditation, lab books, source data, SOPs and personal training records. • Files on studies which were never started and were not submitted to a REC nor the MHRA do not need to be retained. • Files on studies which were submitted to a REC and/or the MHRA but never opened to recruitment should be retained locally for two years from the date of REC/ MHRA approval (if both approvals were awarded, use the later date). • Files on studies which received REC and/or MHRA approval and opened to recruitment but did not recruit should be archived as per table above. Barts Health research study records must be archived with the Barts Health Corporate Records Team. It is strongly advised that Queen Mary clinical research records are archived with the Barts Health Corporate Records Team, but there is a charge for this service (please see *Associated Document 1 Corporate Records Management guidelines*). Queen Mary studies may be stored in-house or with an external provider, but these arrangements must comply with Queen Mary's Records Retention Policy and records management procedures, available via: https://arcs.qmul.ac.uk/governance/information-governance/records-management/.
6.	CI/ PI or delegate	**Put appropriate arrangements to archive electronic materials.** For Barts Health and Queen Mary sponsored studies, electronic archiving solutions must be approved by the JRMO. Please send the system specification, validation documents, security and backup information, name of archivist and physical location of the archiving servers to the JRMO for review. Should an organisational wide e-archiving process be developed during the life span of this SOP, this step will not be needed for individual studies. If the solution is provided by an external vendor, a contract will be put in place between the sponsor and the vendor. For MHRA regulated studies, a vendor assessment must be completed by the JRMO prior to the contract being signed or a decision made (see *SOP 40 Vendor assessment*). In this instance, for Interventional and Research studies, a vendor assessment would be considered best practice. For hosted studies, if the sponsor provides an electronic archiving system, please notify the JRMO of this during C&C If an acceptable electronic archive is not available, print out all electronic essential documents and archive them with the paper documents. If you have digital R&D records that need to be saved as part of a study, please contact records.management@nhs.net for details of the digital archive solution.
7.	Research Governance and GCP manager	**Assess electronic archive documentation and approve or decline the use of the archive.**

Uncontrolled if printed

	(MHRA-regulated studies) or Research Management Team Leader (Interventional and Research studies)	Confirm that the system specification meets the requirements of an electronic archive, that the system has been fully validated, that security and backup processes are appropriately robust and that the storage arrangements do not contradict what has been stated in the study documentation. For MHRA regulated Barts Health/Queen Mary sponsored studies where the solution is provided by an external vendor, ensure that a vendor assessment has been completed and that a contract is in place. For Interventional and Research studies, a vendor assessment would be considered best practice. Note that some vendors may already provide their archiving solution to other Barts Health or Queen Mary studies. In this case, a proportionate approach to a repeated assessment may be taken.
8.	CI/ PI or delegate	**Follow the Corporate Records guidelines to archive paper materials.** The Corporate Records guidelines must be followed, and the provided forms must be used (available on request from Corporate Records, records.management@nhs.net). The designee should pack the boxes and complete the relevant paperwork. If details are requested for the location of files, please use the below text in full: All Barts Health records are managed (oversight, retrieval and destruction) by the Corporate Records team at Barts Health NHS Trust . Please contact records.management@nhs.net. Files storage is outsourced to : Crown Records Management 2 Brunel Way Segensworth East Fareham Hampshire PO15 5TX See *Associated document 1 Corporate Records Management guidelines* for further details.

Uncontrolled if printed

Change control

This section outlines changes from version **6.0** to version **7.0**

Section changed	Summary and description of changes
Throughout	Administrative changes
Section 6 and 7	Clarification on vendor assessments for electronic archiving systems for Interventional and Research

List of associated documents

Document ref.	Document name
1	Corporate Records Management guidelines to archive paper materials.

Uncontrolled if printed