Standard Operating Procedures (SOP) for:			
Transferring Research Project Records to Corporate Records Management (known as Archiving)			
SOP Number:	***20***	Version Number:	***5.0***
Effective Date:	***03rd September 2015***	Review Date:	***02nd September 2017***

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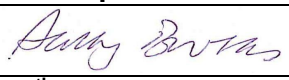
Signature:	
Date:	**13th August 2015**

Purpose and Objective:
To ensure that research project records are transferred into the management of the Corporate Records Management Team for secure long-term storage at the end of each project, to comply with the Research Governance Framework, 2005, the Data Protection Act, 1998 and Barts Health Trust and Queen Mary University of London Policy on the Retention and Disposal of Records (based on Department of Health recommendations on records retention). To aid compliance with MHRA inspections and the Freedom of Information Act 2000 since records and information can be retrieved quickly when needed. To ensure that research records are managed in the most cost effective and secure way.
Scope:
All Joint Research Management Office (JRMO) sponsored and hosted research projects taking place within Barts Health NHS Trust and Queen Mary, University of London. This SOP does not apply to contracted work from East London NHS Foundation Trust. Please see ELFT held policies for guidance.

Abbreviations:	
BH	Barts Health NHS Trust
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare Regulatory Agency
PI	Principal Investigator
QMUL	Queen Mary University of London
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TMF	Trial Master File

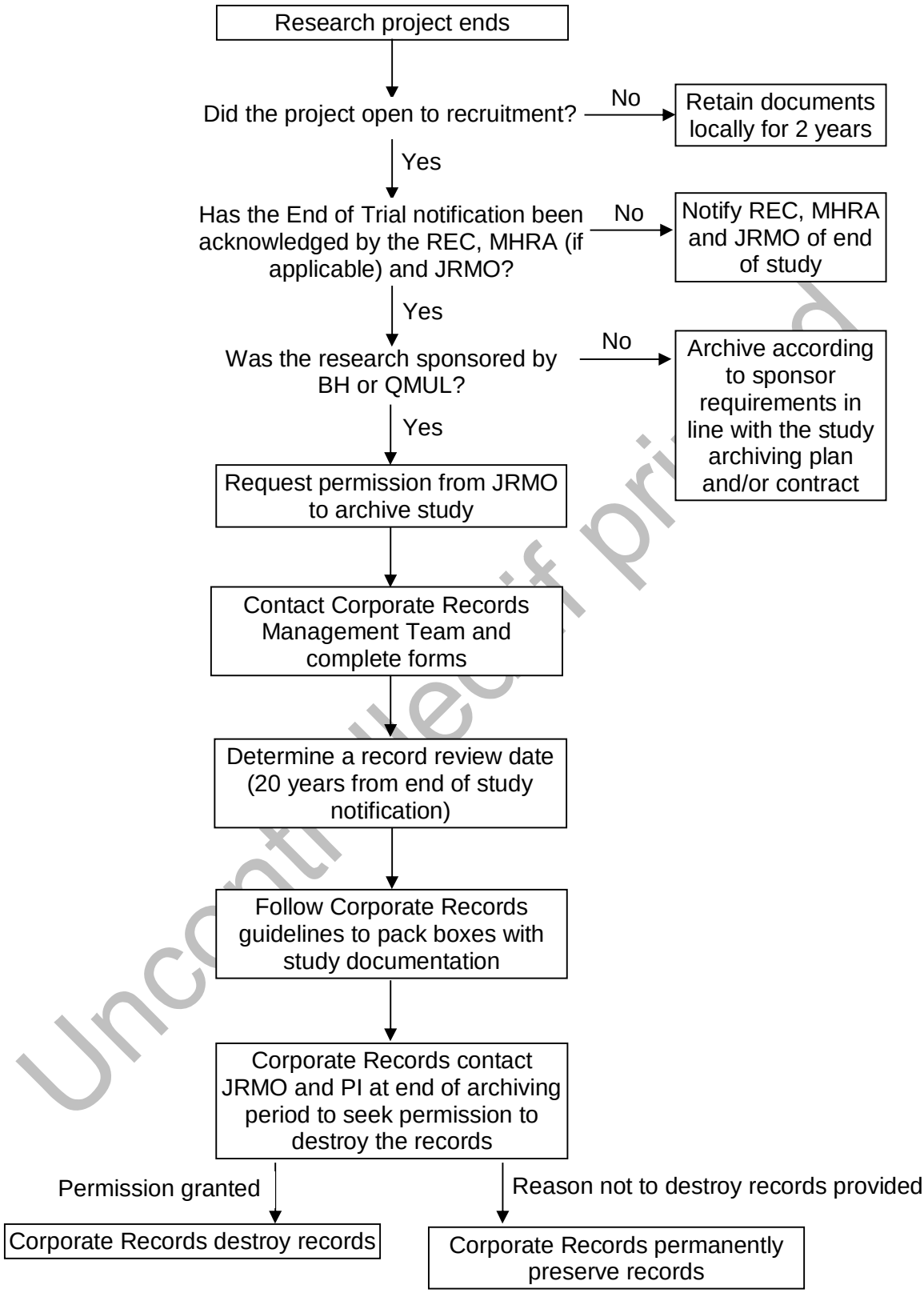
Definitions *(if needed):*
Not needed.
Relevant SOPs:
JRMO SOP 18a Project closure: guidance for research staff of sponsored studies JRMO SOP 18a Project closure: guidance for research staff of hosted studies JRMO SOP 19 Project closure: guidance for JRMO staff

SOP Text		
	Responsibility	Activity
1.	ALL	**At the completion of the study, archive all study documentation for 20 years.** Both QMUL and BH retention policy indicated that research files should be retained for 20 years. Please note that: • Files on projects which were never started and never went to either a Research Ethics Committee (REC) or the Medicines and Healthcare products Regulatory Agency (MHRA) do not need to be kept. • Files on projects which a REC and/or the MHRA and the JRMO approved but never opened to recruitment should be kept for two years. • Files on projects which received REC and/or MHRA approval and JRMO approval and opened to recruitment, but did not recruit (may/may not have screened subjects) and then was closed, should be archived for the full 20 year period. Research records will be sent to the Barts Health Corporate Records Management Team that are: • Related directly to BH patients, • Not in current use (no longer 'active'), • Required to be kept for more than 2 years. If records need to be kept for 2 years or less then the documents must be retained locally. Projects involving QMUL are advised to archive with the BH Corporate Records Management Team, but there is a charge for this service (please see associated document 1).
2.	Principal Investigator (PI)	**Once the End of Study notifications have been acknowledged, ensure the documentation is present and complete, and obtain permission to archive from Sponsor.** Clinical trial documentation should be archived in a timely manner following completion of a trial, by a designee(s) as documented on the study delegation log. When an investigator receives confirmation that a study file can be archived, reference should be made to the study contract, clinical trials agreement and/or archiving plan if available. These will specify who is responsible for archiving the study and any specific instructions related to this. When a request to archive a trial file is made by the sponsor, the PI or the designee should confirm that all essential study-related material is present and complete, and this must include retrieval of the pharmacy file (if possible) and any trial-specific laboratory files. For BH and QMUL sponsored CTIMPS a request should be made to the Research Governance and GCP manager in writing for

		permission to archive. Prior to commencing the archiving process, the PI must ensure that end of study notifications have been sent and acknowledged by the REC, MHRA (if applicable) and the JRMO. Inform the JRMO that permission to archive has been obtained. If any documents are filed separately from the main study file(s), then a file note should be made to be included in the Trial Master File (TMF) detailing where the document is stored, for example in a patient's medical records.
3.	Research Governance and GCP manager	**Research Governance and GCP managers will ensure the JRMO records are present and complete.** For BH and QMUL sponsored CTIMPs the following should be checked prior to permission to archive being given: • Documentation present in file to demonstrate end of trial notifications submitted (for both MHRA and REC) and acknowledgments. • End of Study report present. • ReDA updated to reflect status • JRMO file passed to relevant staff to archive.
4.	Clinical Trials Co-ordinator, or person nominated by PI to transfer the records	**Follow the Corporate Records Management guidelines to archive materials.** The Corporate Records Management guidelines and the forms they provide must be followed (available on the BH intranet or on request from Corporate Records). The designee should pack the boxes and complete the relevant paperwork. The following is a summary of the process: • Only archive boxes provided by the Corporate Records Management Team must be used. • Each box holds approximately 10 slim A4 folders or 3 A4 lever arch files. Box dimensions are 37x29x19cms. • Fill the boxes following Corporate Records Management guidelines. Complete a transfer form; specific information about each project is needed: full title of project, name of PI, name of sponsor, ReDA number (if known), types of document in each box, and end date of each project (also start date, if known). Without this information the files will not be accepted. • Records should not be stored on USB sticks or other digital storage media. • Once the boxes are ready, email the completed transfer form to the Records Management team who will check the form and organise transport. • Records Management team will arrange for the boxes to be collected and transported. • Investigator will receive a records transfer receipt; this should be retained by the PI as this can be referred to if any records are required in future. Records Manager/

		Assistant Records Manager to retrieve and loan records to depositing office, when required.
5.	Records Manager / Assistant Records Manager	**Determine a record review date.** Set a date when the records will be reviewed (in accordance with Trust Policy on the Retention and Disposal of Records), or in discussion with the PI and in accordance with QMUL retention policy.
6.	Records Manager / Assistant Records Manager	**Corporate Records will contact the JRMO, PI and Sponsor to request destruction at the end of the archiving period.** When the records have reached the end of their retention period, Corporate Records will follow their own internal SOPs regarding destruction. The Corporate Records team will contact the JRMO, PI and sponsor informing them of the records due for destruction and will inform them that this will occur by a specified deadline unless there is any justified reason put forward for retaining for a longer period.
7.	PI (or relevant member of staff from the depositing office if PI has left the Trust) and Sponsor.	**Notify the Records Management team if the responsibility for the study files changes, and advise them if there is a particular reason to retain the records at the end of the archiving period.** If the PI leaves Barts or QMUL during the archival period, arrangements must be made to ensure the safekeeping and security of the archive information. Also, changes in personnel must be defined in the study file and any handover of responsibility must be documented. The sponsor and Corporate Records team must also be informed of the new arrangements. This is the responsibility of the PI. When contacted by Records Management team at the time of destruction, advise if there is any particular reason to retain the records, e.g. ongoing litigation or significant historical reference value. Consideration should be given to the Data Protection Act, since personal data should not be kept for longer than necessary.
8.	Records Manager / Assistant Records Manager	**Corporate Records will destroy records or permanently preserve them as appropriate at the end of their archiving period.** Once the pre-advised deadline for destruction of records has passed and assuming no objections were raised, destroy the records as confidential waste and log the destruction on disposal register (database). If appropriate, arrange for the Archivist to appraise the records to see if they are worthy of permanent preservation in the Trust Archives for historical research.

Flow Chart



Change Control

This section outlines changed from version 4.0 to version 5.0.

Section Changed	Summary and description of change
All	Spelling, punctuation, grammar and phrasing.
Reviewer	Matthew Hall added.
Abbreviations	Added.
Relevant SOPs	Added.
1	Heading added. Reference to associated document 1 added.
2	Heading added.
3	Heading added.
4	Heading added. Note added that records should not be stored on digital storage media.
5	Heading added.
6	Heading added.
7	Heading added. Section moved to end of box to fit chronologically.
8	Heading added.

List of Associated Documents *(these are standalone documents)*

	Document name
Associated Document 1	Archiving cost guidelines