Standard Operating Procedures (SOP) for:			
JRMO internal filing process			
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Purpose and Objective:
The purpose of this SOP is to explain: 1. How project records are set up, 2. How project records are maintained and by whom, 3. Where project records are maintained.
Scope:
This SOP outlines how the JRMO will file study documents. No retrospective action will be take on files created prior to this date, unless deemed as necessary.

Abbreviations:	
APR	Annual Progress Report
ATIMP	Advanced Therapy Investigational Medicinal Product(s)
BH	Barts Health NHS Trust
CI	Chief Investigator
CRF	Case Report Form
CTIMP	Clinical Trial of an Investigational Medicinal Product(s)
DSUR	Development Safety Update Report
EOT	End of Trial
GCP	Good Clinical Practice
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare Regulatory Agency
PI	Principal Investigator
QMUL	Queen Mary University of London
REC	Research Ethics Committee
ReDA	Research Database Application
SAE	Serious Adverse Event
SOP	Standard Operating Procedures
SUSAR	Suspected Unexpected Serious Adverse Reaction

Definitions *(if needed)*
Clinical Investigations: Projects involving a non-CE marked medical device. Indemnity: Shared electronic folder containing the JRMO's project records, located on the Barts Health NHS Trust network.

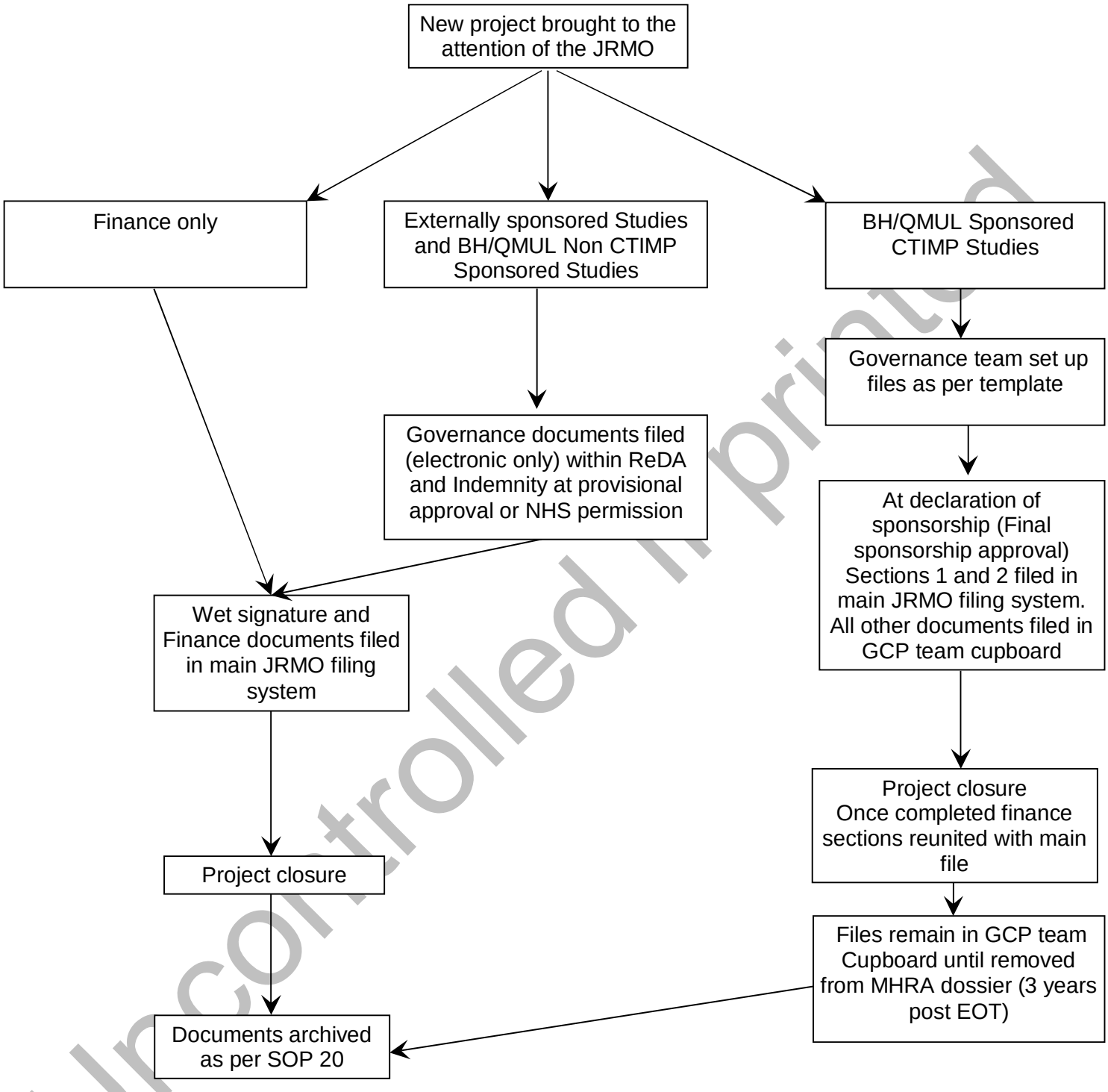
Relevant SOPs
JRMO SOP 18a: Project closure: guidance for research staff of sponsored studies. JRMO SOP 18b: Project closure: guidance for research staff of hosted studies. JRMO SOP 19: Project closure: guidance for JRMO staff. JRMO SOP 20: Archiving for research projects.

SOP text		
	Responsibility	Activity
1.	JRMO Governance Team	**<u>Project records for BH/QMUL Projects (JRMO) are to be kept.</u>** Documentation for <u>externally sponsored projects</u> will be kept electronically only. Note for any documentation with a wet-ink signature (e.g. contracts) these need to be stored in the paper records. For <u>BH and QMUL sponsored non-CTIMPS</u> documentation will be kept electronically only. Note for any documentation with a wet-ink signature (e.g. contracts) these need to be stored in the paper records. <u>For BH/QMUL Sponsored CTIMPs, ATIMPS or Clinical Investigations</u> documents will be maintained in an electronic and hardcopy format as detailed below. Files will be maintained by the GCP team from point of Declaration of Sponsorship. Please see section 4 for details. The governance team will copy the GCP team when approving any BH/QMUL CTIMP, ATIMPs or Clinical Investigations. Records are stored in the JRMO shared drive initially (the source location) in the Indemnity folder (I:\corporate_medical\Research and development\Public\Indemnity Folder). Please see Section 2 for naming conventions. Copies of records are to be filed in ReDA – under the document store for that project – refer to the ReDA manual.
2.	All JRMO staff	**<u>JRMO staff and researchers are advised it is deemed best practice to follow naming conventions for electronic files.</u>** <u>For BH or QM Sponsored studies:</u> When saving documents (except email correspondence) in Indemnity or ReDA, files should be named as below: YYYY_MON_DD_Type of document_version_Study Short title_ ReDA # Type of document could be protocol, GP letter, meeting notes, SOP etc. When saving email correspondence in Indemnity or ReDA, files should be named as below: YYYY_MON_DD_ EMAIL_ Topic_ Sender Surname Research teams will be encouraged to use and submit documents and files following this method. <u>For externally sponsored studies:</u> Files are to be saved as named by sponsor. Additionally in ReDA a simple description of the document type should always be inserted when saving documents.

3.		**<u>The filing structure below will be followed when new projects are set up in Indemnity and/or ReDA.</u>** When a new project is set up, the project file in the shared drive (under Indemnity) must be ordered following the <u>JRMO files contents page</u> (see Appendix A). A template of this set up can be found In the Indemnity folder under TEMPLATES. This set of folders is automatically generated in ReDA when a new project is added. **Amendments** Amendments will be filed within subfolders, which will be named using the format: YYYY_MON_DD_ Amendment 1_ Substantial or Minor. The date is the date of submission to REC and / or MHRA. Please See SOP 17a on amendments. **Correspondence** Correspondence should be filed within the relevant subject folder, and must only be filed within General Correspondence for topics not already specified.
4.	GCP team	**<u>For Sponsored CTIMPs, Finance, Contracts and Agreements will be filed as usual, but all other sections will be filed within the GCP cupboards.</u>** For Sponsored CTIMPs, Sections 1 and 2 of the paper files will be filed within the main JRMO filing system. Sections 3-11 will be filed in one of the GCP team designated cupboards according to associated document 1.
5.	GCP and Governance teams	**<u>Records of pertinent study correspondence will be retained.</u>** Correspondence about key decision making for the conduct of the study should be retained. Emails should be saved within the shared drive as well as a paper copy where indicated on the sponsor oversight files CTIMP content page. Key decision making correspondence includes, but is not limited to: • Protocol design (including during set-up stage), • Evidence of regulatory submissions (including amendments), • Evidence of reporting of serious breaches, SAEs, SUSARs, DSURs, APRs, • Correspondence with support departments (e.g. imaging, clinical physics, pharmacy), • Contractual decisions, • Monitoring report correspondence between the JRMO, sites and CI's team, • Any other key decisions which could impact on the trial design or conduct, participant safety, or data integrity.

6.	All JRMO staff	**Projects will be named using the lead researcher's name and the project ReDA number.** Projects are saved by: • Folder named as the lead researcher (CI/PI)* surname, followed by first name, • Subfolder named with the project ReDA number. *If the sponsor is BH/QMUL then the CI is the lead researcher; if BH/QMUL is a host site then the PI is the lead researcher. For paper files (each project is to have its own ReDA number), GCP Files will be labelled as per Associated Documents 2 and 3. If these files are split, these should be numbered (1 of 2, 2 of 2, etc.).
7.	Governance team	**Inspection preparation** In case any file is required for audit or inspection the Governance Operations manager will allocate a Governance section staff member to create a hard copy of the file which will be presented for inspection.
8.	Staff working on UCLP harmonisation projects	**Projects being set up as part of the UCLP Harmonisation will be filed initially by IRAS number and study title.** Once the Barts Health NHS Site receives NHS permission, the Barts Folder will be added to the PI's Indemnity folder. Non BH project documentation will remain within the Harmonisation folder / Indemnity.
9.	All JRMO staff	**Projects in the Pending Approval, Active and Closed phases:** A project goes through three phases during its life cycle. The JRMO paper records are separated accordingly: ***Pending approval*:** Unless only financial records have been received, projects pending final approvals are kept in the pending file location(s). When there are financial documents only, the project documents will be filed within the main JRMO filing system. ***Active (has Governance Approval/Permissions)*:** Projects that have gained final approvals (or finance only if Governance approvals are not applicable) are kept in the active file locations. ***Closed projects*:** Projects that have no outstanding 'governance' or 'finance' activity are to be archived. Refer to JRMO SOP 18a (Project closure: guidance for research staff of sponsored studies), JRMO SOP 18b (Project closure: guidance for research staff of hosted studies), JRMO SOP 19 (Project closure: guidance for JRMO staff), and JRMO SOP 20 (Archiving for research projects). For electronic files: All documents must be uploaded to ReDA and Indemnity either when NHS permission is granted or, if BH/QMUL sponsored, at Provisional Sponsorship stage.

10.	R&D Governance Operations Manager, Governance Partnership Coordinator	**Legacy Records** (for projects prior to the BH merger on 1st April 2012): There are currently four JRMO office locations (Newham, Whipps Cross, Whitechapel and Mile End). Prior to the 2012 merger, records were stored at each R&D office with varying methods for record keeping. Whipps Cross and Newham R&D projects that were active as of 1st November 2011 have been mapped onto ReDA and electronic files have been updated on indemnity as per JRMO policy. Paper project records of active studies are to be merged with those held in JRMO. R&D project files at each locality (R&D office) which closed prior to 31st March 2012 are to be archived in accordance with previous SOPs for that institution. Any remaining paper records for studies that had closed and had not been archived by the legacy Trusts are to be archived in the Modern Records Department at Prescott Street. Electronic R&D records for legacy projects will continue to be accessible to JRMO staff. R&D records for CTIMP studies must be retained for the recommended time as stipulated in the JRMO SOPs (please see JRMO SOP 20 on Archiving for further information). A master list of legacy projects will be available on request from the JRMO. Corporate R&D records from the legacy Trusts will remain at their current locations and will be archived in due course.



Change Control

Document created at version 1.0. No changes to implement.

List of appendices

	Document name
Appendix A	JRMO files contents page

Appendix A JRMO files contents page

1. Finance
2. Contracts &and agreements
3. Initial study approvals *(to keep all paperwork that allowed for final governance approvals)*
    a. *JRMO*
    b. *REC*
    c. *MHRA*
    d. *Other*
4. Amendments (paperwork subsequent to the initial approval)
5. Safety and pharmacovigilance
6. Annual reports
7. Study management documents (*this is for project specific manuals, tools*)
8. Monitoring and Audit
9. Non-conformance
10. End of trial
    a. EOT notifications
    b. Final report
11. General Correspondence

List of Associated Documents

	Document name
Associated Document 1	Governance file template
Associated Document 2	GCP file spine template
Associated Document 3	GCP file cover template