Joint Research Management Office Standard Operating Procedure for:			
JRMO Internal Governance documentation filing process			
SOP Number:	**27**	Version Number:	**2.0**
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Purpose:

The purpose of this Standard Operating Procedure (SOP) is to explain:

1. How the Joint Research Management Office (JRMO) clinical study files are set up.
2. How clinical study JRMO records are maintained and by whom.

Note: This SOP does not apply to non-clinical studies

Scope:

This SOP outlines how the JRMO Governance Section will file clinical study documents. No retrospective action will be taken on files created prior to the SOP effective date, unless deemed necessary.

This SOP is only applicable to internal clinical study filing within the JRMO Governance Section. For all other clinical study filing (such as creating of a Trial Master File (TMF)) please see SOP 45 Study specific essential file documentation.

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Abbreviations:	
APR	Annual Progress Report
Barts Health	Barts Health NHS Trust
CRN NT	Clinical Research Network North Thames
CE	Conformité Européenne
CI	Chief Investigator
DSUR	Development Safety Update Report
EDGE	EDGE
EOT	End of Trial
GCP	Good Clinical Practice
HRA	Health Research Authority
IRAS	Integrated Research Application System
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
SAE	Serious Adverse Event
SOF	Sponsorship Oversight File
SOP	Standard Operating Procedures
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File

Definitions:

Clinical Investigations: Studies involving a non- Conformité Européenne (CE) marked medical device or a device used outside the scope of its CE marking, where there is potential to commercialise the device.

Indemnity Folder: A shared electronic folder containing the JRMO's clinical study records, on drives controlled by the Queen Mary University of London (Queen Mary) network.

TMF is the main file for a clinical study. Its maintenance is delegated to the Chief investigator (CI) and should contain all documentation essential to fully reproducing the clinical study.

JRMO clinical study files or JRMO sponsor oversight files (SOF) are kept and maintained with the intention to provide evidence of sponsor oversight of ongoing studies. There will be duplication between the TMF and SOF.

Relevant SOPs:	
• SOP 18a • SOP 18b • SOP 45	Study closure: Sponsored MHRA-regulated studies Study closure for Interventional, Research and Hosted Studies Study specific essential file documentation.

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SOP Text:		
	Responsibility	**Activity**
1.	Governance section member	**Does an EDGE entry exist for the clinical study** On notification of a new clinical study, complete a thorough EDGE search to check whether an EDGE entry already exists. Run searches on key phrases in the clinical study title and check through all the CI's studies on EDGE (please refer to EDGE manual for more details). This can be on submission of a study dataset or at early engagement. The user must populate the EDGE entry with all of the study information that they currently have available (minimum dataset as per the EDGE user manual).
2.	Governance team member	**Generate electronic files for new studies in the Indemnity folder as per JRMO filing conventions.** Once an EDGE entry has been created, an electronic file must be created for the clinical study in the Indemnity Folder. The Indemnity Folder contains a file for each lead researcher (CI or Principal Investigator (PI)). The clinical study folder should be saved inside the lead researcher's folder. If the clinical study is led by a new researcher, then a new lead researcher folder should be created, and the clinical study folder saved inside. The clinical study folder must be named with its Integrated Research Application System (IRAS) number (EDGE ID if there is no IRAS ID) and short title if it's a sponsored Medicinal and Healthcare Regulatory Agency (MHRA) regulated clinical study. The clinical study folder must be ordered following the JRMO sponsor oversight files contents page (see Appendix A) or JRMO hosted Study Oversight files contents page (Appendix B). A template of this set up can be found in the Indemnity folder under TEMPLATES. All documents saved electronically must be saved with a file name containing (as a minimum): Type of document Version and /or DD.MM.YYYY Clinical Study Short title or IRAS number For example: • Smith A,_CI_CV_01.01.2020_Research study • Study name/IRAS number Protocol v1.0_120789 Additional guidance for newly generated clinical study documents: **1. General Documentation** Type of document version Clinical Study Short title or IRAS number DD.MM.YYYY For example:

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		• Protocol_v1.0 _20789_01.01.2020 **2. Amendment Documentation** Amendments will be filed within subfolders, which will be named using the format: Amendment No_Substantial or Non-Substantial Amendment_DD.MM.YYYY The date is the date of amendment as per the amendment form or Research Ethics Committee (REC)/Health Research Authority (HRA) approval. For example: • Amendment 1_Substantial_01.06.2020 3. **Correspondence** When saving email correspondence, files should be named as below: Topic_Sender Surname_DD.MM.YYYY For example: • Confirmation of Sponsorship_Biddle_01.04.2020 Pertinent correspondence should be filed within the relevant subject folder and must only be filed within General Correspondence for topics not already specified (See Associated Document 1 Sponsor Oversight Files Guidance, Associated Document 2 Monitoring filing guidelines and Associated document 3 Hosted Study Oversight Files Guidance). Staff should assess which correspondence to retain as described in section 4 of this process. **Uploading documents to EDGE:** Only the final HRA approved document set, and all necessary approvals should be uploaded to EDGE.
3.	Governance team member	**Generate electronic SharePoint files for new studies (Barts Health NHS Trust (Barts Health)/Queen Mary) sponsored MHRA regulated studies only).** For Barts Health/Queen Mary Sponsored MHRA regulated studies, where applicable, electronic SharePoint SOF files should be maintained in addition to indemnity electronic files. Files will be maintained by the Good Clinical Practice (GCP) team from the point of confirmation of sponsorship. For further guidance see Associated Document 1 Sponsor Oversight Files Guidance, Associated Document 2 Monitoring filing guidelines, Associated document 3 Hosted Study Oversight Files Guidance and Associated Document 4 SharePoint Filing guidance for MHRA regulated studies.

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		Please note, Barts Health/Queen Mary sponsored MHRA regulated studies set up before September 2021 will still have paper files and are to be maintained as per the above associated documents.
4.	GCP and Governance teams	**Assess which correspondence to retain.** Correspondence about key decision making for the conduct of the clinical 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 content page. Key decision-making correspondence includes, but is not limited to: • Protocol design (including during set-up stage), • Evidence of regulatory submissions (including approvals and amendments), • Evidence of reporting of serious breaches, Serious Adverse Event (SAE), Suspected Unexpected Serious Adverse Reaction (SUSAR), Development Safety Update Report (DSURs), Annual Progress Report (APR), • Correspondence with support departments (e.g., imaging, clinical physics, pharmacy, pathology). • Contractual decisions, • Monitoring report correspondence between the JRMO, sites and CI's team, • Any other key decisions which could impact on the clinical study design or conduct, participant safety, or data integrity.
5.	Governance team	**Inspection preparation for all studies** In case any file is required for audit or inspection the Governance Operations manager will allocate a Governance section staff members to create and/or update a hard copy of the file which will be presented for inspection.
6.	Research Governance Operations Manager	**Oversight of Archiving clinical study documentation** Work with Research Governance and Performance Manager, GCP & Governance Manager and Office Manager to ensure JRMO governance files are archived appropriately. Studies that have no outstanding 'governance' or 'finance' activity are to be archived. Refer to SOP 18a Study closure for sponsored MHRA regulated studies, SOP 18b Study closure for Sponsored Interventional, Research and Hosted Studies.

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Change control

This section outlines changes from version **1.0** to version **2.0**

Section changed	Summary and description of changes
Section 7	Removal of NIHR portfolio study reference
Section 9	Removal of legacy records reference
Associated document	New associated document for hosted studies
Associated document	New associated document for SharePoint Filing guidance for MHRA regulated studies
Appendix	New appendix for hosted studies

List of appendices

Appendix reference	Appendix name
Appendix A	JRMO sponsor oversight files contents page
Appendix B	JRMO hosted Study oversight files contents page

List of associated documents

Section changed	Summary and description of changes
Associated document 1	Sponsor Oversight File Guidance
Associated document 2	Monitoring filing guidelines
Associated document 3	Hosted Study Oversight Files Guidance
Associated Document 4	SharePoint Filing guidance for MHRA regulated studies.

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Appendix A

JRMO sponsor oversight files contents page

1. Finance
2. Contracts and agreements
3. Initial clinical 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. APRs
7. Clinical Study management documents (*this is for clinical study specific manuals, tools*)
8. Monitoring and Audit
9. Non-compliance
10. End of trial (EOT)
    a. EOT notifications
    b. Final report

Appendix B

JRMO hosted Study Oversight files contents page

1. Costing and Contracts
2. Governance Capability and Capacity
    a. Clinical Director Authorisation
    b. CVs and GCP certificates
    c. Supporting Departments
    d. Document pack
    e. AAC review
    f. Trust Authorisation
3. Confirmation of Capacity and Capability
4. Amendments
5. Noncompliance
6. Reports
7. End of trial

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