JRMO Sponsor Oversight Files
The responsibility of the governance section unless otherwise flagged

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Abbreviations

AAC	Arrange Assess and Confirm	PAF	Portfolio Application Form
APR	Annual Progress Report	PI	Principal Investigator
CI	Chief Investigator	PV	Pharmacovigilance
CV	Curriculum Vitae	REC	Research Ethics Committee
DSUR	Development Safety Update report	ReDA	Research Database Application
GCP	Good Clinical Practice	RSI	Reference Safety Information
HRA	Health Research Authority	SA	Substantial Amendment
IB	Investigators Brochure	SAE	Serious Adverse Event
ICF	Informed Consent Form	SIV	Site Initiation Visit
IMP	Investigational Medicinal Product	SmPC	Summary of Product Characteristics
IRAS	Integrated Research Application System	SOP	Standard Operating Procedure
JRMO	Joint Research Management Office	SUSAR	Suspected Unexpected Serious Adverse Reactions
MHRA	Medicines and Healthcare Products Regulatory Agency	TMF	Trial Master file
NIHR	National Institute for Health Research	UAT	User Acceptance Testing
NSA	Non-Substantial Amendment		

Folder	Sub folder layer 1 Title	Sub Folder layer 2 Title	Content/examples	Location	Comment
1. Finance	***n/a***			• Paper file/SharePoint • Worktribe	Responsibility of post award
2. Contracts	**a) Vendors**	**By vendor name**	Final Signed contracts plus vendor assessment	**MHRA regulated studies:** • Work tribe • Indemnity/EDGE • Paper File/SharePoint **All other study types:** • Indemnity • EDGE only	Responsibility of pre-award
	b) Sites	**By site name**	Final signed contracts		Responsibility of pre award
	c) Statement of Activities		Final agreed versions		

Folder	Sub folder layer 1 Title	Sub Folder layer 2 Title	Content/examples	Location	Comment
3. Initial Approval	**a) Early Engagement**		Any engagement prior to initial study submission	**MHRA regulated studies:** • Indemnity • EDGE • Paper file/SharePoint **All others study types:** • Indemnity • EDGE In this section print a full copy of: a. the version of documents submitted to the JRMO and b. version approved by the JRMO for regulatory submission and c. the final approved versions	
	b) NIHR (Delete if N/A)		- PAF - Eligibility email Any NIHR related correspondence		
	c) Study Documents	**Superseded**	- IRAS - Protocol - PIS - ICF - Any other patient facing documents		
	d) CV & GCP	**CI** **Research Team**	CV & GCP including course booking confirmation		Sponsored studies save in the CI folder Hosted studies save in the Research team folder
	e) Scientific & Department Review		Scientific Review Departmental Authorisation - Any related correspondence		
	f) Support Departments	**Create subfolders as required**	Correspondence and confirmation of approval for: - Pharmacy - Imaging - Pathology - Costing & Contracts - Medical Physics - Information Governance - Other approvals		Please note Costing and Contract is always required. (at minimum confirmation not required)

Folder	Sub folder layer 1 Title	Sub Folder layer 2 Title	Content/examples	Location	Comment
Initial approval continued	**g) Database**			**MHRA regulated studies:** • Indemnity • EDGE • Paper file/SharePoint **All others study types:** • Indemnity • EDGE In this section print a full copy of: d. the version of documents submitted to the JRMO and e. version approved by the JRMO for regulatory submission and the final approved versions	
	h) IMP Device (Delete if N/A)		Reference Safety Information SmPC Device Certificates Any other related documents/ correspondence		NB submission documents
	i) MHRA Regulated Study (Additional documents) (Delete if N/A)		Kick off meeting /correspondence		
	j) Risk Assessment		Completed Risk Assessment		
	k) Sponsorship Statements		CI /sponsor agreement Letter of Sponsorship with conditions Letter of Confirmation of Sponsorship Any related correspondence		These can be in email or letter format as per SOP
	l) REC approval & correspondence		Approvals and related correspondence/ documents		
	m) MHRA approval & correspondence		Approvals and related correspondence/ documents		
	n) HRA approval & correspondence		Approvals and related correspondence/ documents		
	o) Capacity & Capability (Delete if N/A)	-	- Trust Authorisation - AAC Form - Clinical Director Authorisations Any related correspondence		Delete ONLY if Barts Health or Queen Mary is not a site.

Folder	Sub folder layer 1 Title	Sub Folder layer 2 Title	Content/examples	Location	Comment
4. Amendments	**a) *Pre Approval* (Delete if N/A)**			**MHRA regulated studies:** • Indemnity • EDGE • Paper/SharePoint **All others study types:** • Indemnity • EDGE	
	b) SA1 dd.mm.yyyy	**-**	GCP manager approval (happy to submit Amendment) Full Submission (including clean and tracked version of all documents) REC approval MHRA approval Barts Health Acknowledgement (if Barts Health site only)		For each amendment create a new folder Please date amendments as per HRA approval letter as where possible
	c) NSA 1 dd.mm.yyyy	**-**			
	d) Amendment log (Del if N/a	**-**			Applicable when Summary monitoring repost are being received
5. SAE/ SUSAR	**a) SAE**		Saved by event	**All studies:** SAE and SUSAR forms and correspondence is logged within ReDA and documents filed within Indemnity **MHRA regulated Studies only:** Log only is printed - either at receipt of summary report of every monitoring visit	
	b) SUSAR				
	c) SAE Log				
	d) PV related		PV related procedures		

	Folder	Sub folder layer 1 Title	Sub Folder layer 2 Title	Content/examples	Location	Comment
6.	**Annual reports**	**a) Annual Progress Reports**	**APR/DSUR by year**		Drafts and approvals filed electronically with in Indemnity file only and logged in EDGE workflows	
		b) DSUR (Delete if n/a)				
7.	**Study management document**	**b) IMP**	**RSI**	Per IMP by version: IB or /and SmPCs (as was submitted to MHRA)	**MHRA regulated studies:** • Indemnity • Paper/SharePoint **All others study types:** • Indemnity	Sample prescriptions can be found in TMF
			IMP management plan			
			IMP manual			
			End of trial activity			
			Details of sponsor Agreement for destruction/recall			
		c) Study Team		Contacts for coordinator team. Or delegation log		Please use template
		d) Trial Committee	**Folder by committee e.g. Trial steering committee**	Minutes, Charter		Declaration interest , CV and GCP training is located in the TMF
		e) Computer systems	**Specifications**			NB all documents for all versions
			UAT			
			Go live documentation			
			JRMO agreement			
		f) General Study Procedures				For example, OOO, randomisation SOPs etc.

	Folder	Sub folder layer 1 Title	Sub Folder layer 2 Title	Content/examples	Location	Comment
8.	**Monitoring & Audit**	**a) Monitoring Plan**		Monitoring plan (drafts, final and correspondence)	**MHRA regulated studies:** • Indemnity • Paper/SharePoint **All other study types:** • Indemnity	
		b) Monitoring activity	**Reports from SIV onwards- per year**			Barts Health SIV should be filed
			Per year - Summary reports			
			Monitoring deviations			
		c) Audit		*Audit certificate only.* *Audit reports are not filed here but are available on request*	**MHRA regulated studies:** • Indemnity • EDGE • Paper/SharePoint **All other study types:** • Indemnity • EDGE	
9.	**Non-compliance**	**a) Events**	**By NC number**	Individual event documentation	**MHRA regulated studies:** • Indemnity • Paper/SharePoint **All other study types:** • Indemnity	Please log per event by date
		b) Non-compliance log		Correspondence and Forms as applicable		NB when sent by team e.g. In summary report.

Folder	Sub folder layer 1 Title	Sub Folder layer 2 Title	Content/examples	Location	Comment
10. End of trial	**a) REC:**	**-**	Cover letter End of trial notification Acknowledgment	**MHRA regulated studies:** • Indemnity • EDGE • Paper/SharePoint **All other study types:** • Indemnity • EDGE	
	b) MHRA:	**-**	Cover letter End of trial notification Acknowledgment		
	c) Clinical Study Report	**-**	Include reminders, drafts, approval and final versions		
	d) Publications /abstracts/dissemination (If applicable)	**-**			
	e) Archive	**-**	Permission to (and location of)		