JRMO Hosted Oversight Files
The responsibility of the governance team unless otherwise flagged

Contents

Abbreviations

AAC	Arrange Assess and Confirm
CV	Curriculum Vitae
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare Products Regulatory Agency
NSA	Non-Substantial Amendment
OID	Organisational Information Document
QA	Quality Assurance
REC	Research Ethics Committee
SA	Substantial Amendment
SOECAT	Schedule of Events Cost Attribution Template

Filing folder content

Folder	Sub folder layer 1 Title	Content/examples	Location	Comment
1. Costing and Contracts		• Final Signed contracts • SOECAT (draft and validated) OID • Pertinent correspondence	**All study types:** • Indemnity • EDGE Only	Responsibility of pre-award
2. Governance Capability and Capacity	**a)** Clinical Director Authorisation		**All study types:** • Indemnity/SharePoint • EDGE	
	b)CVs and GCP certificates	CV & GCP including course booking confirmation		
	c)Supporting Departments	Correspondence and confirmation of approval for: • Pharmacy • Imaging • Pathology • Costing & Contracts • Medical Physics • Information Governance • Other approvals		
	d) Document pack			
	e) AAC review			
	f) Trust Authorisation			

3. Confirmation of Capacity and Capability		• Confirmation email • Pertinent correspondence		
4. Amendments	**a) *Pre Approval* (Delete if N/A)** **b) SA1 dd.mm.yyyy** **c) NSA 1 dd.mm.yyyy**	• Full Submission (including clean and tracked version of all documents) • REC approval • MHRA approval • Barts Health Acknowledgement (if Barts Health site only)	**All study types:** • Indemnity • EDGE	
5. Non-compliance	**a) Events**	Individual event documentation	**All study types:** • Indemnity	Responsibility of the QA Manager
6. Reports	**Ad hoc dependant on reports submitted**		**All study types:** • Indemnity	Can be used for Pharmacovigilance, annual reports funder report as submitted
7. End of trial	**a) REC:**	• Cover letter • End of trial notification Acknowledgment • Pertinent correspondence	**All study types:** • Indemnity	Responsibility of the Governance Team
	b) MHRA:	• Cover letter • End of trial notification Acknowledgment • Pertinent correspondence		
	c) Clinical Study Report	• Include reminders, drafts, approval and final versions		

		• Pertinent correspondence		
	e) Archive	Permission to (and location of)		