

Joint Research Management Office Standard Operating Procedure for:

Contracting for Interventional and research Studies

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Purpose:

This Standard Operations Procedure (SOP) provides a process to show the responsibilities and journey for the management of pre-award contract administration. This is deliberately designed not to be over-prescriptive due to the wide variety of contracts available, from Heads of Terms, simple Non-Disclosure Agreements to complex commercial, clinical and regulatory studies. The main emphasis lies in the ability of the individual who is either drafting or reviewing a contract to understand and determine risk. The main theme is that a contract is put in place to lessen the risks and liabilities of Parties engaged in business, and the business of a contract officer is to review the inherent risks in the contract clauses including the finances and other schedules.

Scope:

To be used for contracts for Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary).

For this SOP, the definition of Contracted Partner is any legal entity that wishes to enter into a contractual relationship with either Barts Health or Queen Mary.

Most contracts relate to work that will be carried out by a specific Principal Investigator (PI), or Team within a Faculty or Institute as opposed to the whole University or Trust being contracted as a legal entity.

Abbreviations:

Barts Health	Barts Health NHS Trust
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JRMO	Joint Research Management Office
Queen Mary	Queen Mary University of London
SOP	Standard Operating Procedure
PI	Principal Investigator
BD	Business Development (Queen Mary and Barts Health)
RM	Research Manager
LCRN	Local Clinical Research Network
WT	Worktribe Research Management System
Relevant SOPs:	
SOP 7a Contracting for MHRA regulated studies	

SOP Text:		
	Responsibility	Activity
1.	Contracts officer/team	<p>Incoming contracts for review Contracts may come into the office via a number of routes. Directly from PI, Business Development (BD), Local Clinical Research Network (LCRN), External partner and other</p> <p>Determine the specific PI or team to whom the contract relates to ensure allocated to correct Pre-award staff member</p>
2.	Contracts officer/team	<p>Outgoing contracts to draft Contract requests may come into the office via a number of routes. Directly from PI, BD, LCRN, External partner and other</p> <p>Determine the specific PI or team to whom the contract relates to ensure allocated to correct pre-award staff member.</p>
3.	Contract Officer	<p>Worktribe (WT) Registration Set-up a unique record on the WT system. Ensuring all mandatory fields are completed including but not limited to contract type, project lead, contracting parties, risk level, date received and uploading the draft agreement. The costing officer should notify interested parties of the WT unique ID and establish the notes section.</p>
4.	Contract Officer	<p>Determine if there is a financial budget in the contract or schedule</p> <p>If yes, then determine there is a costing in the WT</p> <p>If no costing exists then lead on addressing this with the PI/Research Manager (RM)/Research Team as appropriate</p> <p>The finances must be satisfactorily resolved before the contract can proceed further from this point.</p>
5.	Contract Officer	<p>Determine if this relates to a MHRA regulated study.</p> <p>If yes then see SOP 7a for Contracting for MHRA Regulated Studies.</p>

6.	Contracts Officer	<p>Determine overall risk proportionate to the contracting party (Queen Mary or Barts Health)</p> <p>The costing officer will lead on the risk review. The following clauses may be relevant but are not limited or excluded to the following clauses, this is not an exhaustive list:</p> <ul style="list-style-type: none"> • Background and foreground intellectual property • Publication • Jurisdiction • Warranties and liabilities • Data/material ownership
7.	Contract Officer	<p>Notes and Communication</p> <p>Notes within WT should be updated periodically to ensure all interested parties are informed of contract progress. Status of contract should be updated at various stages until completion of contract signatories.</p>
8.	Contract Officer	<p>Faculty or School authorisation</p> <p>Prior to any contract being allocated to the authorised signatory for final signature, where there is a financial project set-up within WT the officer must ensure that the workflow authorisation has been completed and approved. Where there is no financial element the officer should request authorisation from the faculty or school authoriser via the WT system. This should be recorded within the system</p>
9.	Contract Officer	<p>Pass to the relevant authorised signatory for signature</p>
10.	Operations Manager (Pre Award)/ Director of Research and Development/ Associate Director of Operations or Designated Person	<p>Check and sign the final contract before passing back to the Contracts Officer for distribution.</p> <p>Officer should alert authorised signatory of request for signature and be in a position to provide any information as required.</p> <p>The signatory should check WT / Edge or other systems to ensure all is in order prior to signing.</p>
11.	Contracts Officer	<p>Process fully executed copy of contract.</p> <p>Ensure full execution of contract.</p> <p>Scan contract and save on contract shared drive in JRMO and upload an electronic copy to the EDGE documents where relevant.</p> <p>Ensure Worktribe contracts tab is updated and fully signed contract is uploaded. Where there is a financial element ensure that the post award processes for both QMUL and Barts Health are altered and moved to the appropriate workflow stage in both Edge and Worktribe</p>

Change control

Section changed	Summary and description of changes
All	Administrative corrections throughout and to separate out MHRA regulated studies into a separate SOP.

List of appendices

There are no appendices associated with this SOP.