

Standard Operating Procedures (SOP) for:

Costing and Contracting

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Purpose and Objective:

To map the process for the preparation of costing and contracts.

Scope:

To be used for costings and contracts for Barts Health NHS Trust and Queen Mary University of London. This SOP is mandatory for all sections. Specific mandatory aspects are defined per study type.

For this SOP, the definition of Contracted Partner could be considered to be, but not limited to:

- Funder
- Drug Supplier
- Device Supplier
- Laboratory
- Data Management Company

For the purposes of this SOP the terms Chief Investigator (CI) and Principal Investigator (PI) are used in their governance context meaning CI is overall trial investigator whilst PI is responsible at a site level.

Where the project is non clinical the meaning of PI will be recognised as responsible for the overall project.

Abbreviations:

BH	Barts Health NHS Trust
JRMO	Joint Research Management Office
QMUL	Queen Mary University of London
CTIMP	Clinical Trial of a Medicinal Product
ATMP	Advanced Therapy Medicinal Products

Definitions (if needed)

D&B credit score- Dunn & Bradstreet corp. credit score combines various scoring methods to assess company standings into credit class categories that indicate the level of risk involved with doing business with a particular company. Credit class categories factor in each company's overall financial standing in terms of size, resources and payment histories. Class categories fall within a 1 to 5 ratings scale, with 1 representing low-risk companies and 5 representing high-risk companies. So, companies that fall within the high-risk 5 category would include those that have undergone bankruptcies or have a history of delinquent account activities.

Relevant SOPs

SOP 11b JRMO processes for Sponsorship

SOP 2	Implementing an award
SOP 40	Vendor Assessment

SOP Text

Clinical Trials of Medicinal products, Advanced Therapy and Clinical Investigations trials

	Responsibility	Activity
1.	Chief Investigator (CI)	Contact the Joint Research Management Office (JRMO) to inform them of possible collaboration or service with an external organisation.
2.	Costing and Contracts Team	Request copy of protocol or description of work to ensure all costs are identified at an early stage. Send a copy of the appropriate JRMO Costing Questionnaire to the CI.
3.	Costing and Contracts Team	Attend CTIMP Support Meeting with CI and GCP managers. GCP manager will arrange the CTIMP support meeting to discuss all the management support functions, governance issues, potential study costs, supply of the IMP/ manufacturer of the device for the trial. This meeting will include all parties to ensure that appropriate CTIMP costs are included as per the tab on the Costing Questionnaire titled: 'CTIMP advice.' This will include but is not limited to: <ul style="list-style-type: none"> • Finance • IP • Governance • Contractual relationship.
4.	Costing and Contracts Team	Prepare the costing. Prepare the costing based on information provided, obtaining quotes from various service departments where applicable, ensuring relevant organisational costing methodology is utilised. It is the Costing and Contract Officers responsibility to provide confirmation to the GCP Manager, and Governance Officer that the primary contracts (funding and IMP supply) are in progress with terms agreed, or fully executed).

Once funding secured.

5.	Costing and Contracts Team	<p>Arrange first contracts meeting. Arrange a first contracts meeting: attendees the Costing and Contracts Officer, GCP Manager, JRMO Clinical Trial Monitor, CI, Trial Coordinator/Manager, Pharmacist and/or Medical Physics Expert (device trial only). The CI must be present for the meeting to go ahead.</p> <p>The purpose of the first contract meeting is to identify all contracts required before the Final Declaration of Sponsorship can be given.</p> <p>See SOP 11a for meeting guidance.</p> <p>Contracts Officer is responsible for creating and completing the contract checklist (see Associated Document 1) and sending a draft to the CI for confirmation that all contracts had been identified.</p> <p>A draft contract checklist should be saved within ReDA Documents section.</p> <p>The allocated Costing and Contracts team member is responsible for maintaining the Contract Checklist.</p> <p>Ensure Contract database is updated appropriately.</p>
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6.	Costing and Contracts Team	<p>Commence contract negotiations.</p> <p>Where a new or unknown contracted partner is identified request a company credit check to be carried out. A Credit Check Facility form should be completed and sent to a Credit Control Officer.</p> <p>Negotiations and viability will be based on the risk rating provided by the D&B credit score. The reviewing Contracts Officer and if necessary Credit Control Officer will make this assessment and both rating and assessment will be documented and finance terms adjusted accordingly (See QMUL and BH procurement policy for guidance).</p> <p>Please see SOP 40 Vendor Assessment for other aspects of vendor assessment</p> <p>Vendor assessment should commence as soon as the new vendor is identified and be completed before contracts are commenced.</p>
7.	Costing and Contracts Team	<p>Identify which organisations template should be used.</p> <p>Establish if JRMO template or service provider template should be used and starting point of contract negotiations.</p>
8.	Chief Investigator	<p>Inform external vendor representative of JRMO point of contact.</p> <p>Ensure that any company representative is made aware of the JRMO point of contact for all costing and contractual negotiations who will liaise on behalf of the CI and relevant organisation. Request draft contract to be sent to the JRMO for consideration.</p>
9.	Costing and Contracts Team	<p>Negotiate the price and terms.</p> <p>Negotiate the price and terms with funder or contracted partner. Terms and delegation of duties will be discussed and reviewed by the GCP manager to ensure oversight of regulatory aspects.</p> <p>Due notice should be paid to BH or QMUL insurance policy and scope and if necessary prepare a draft contract using the JRMO's contract suite of templates or review contract sent by provider ensuring all governance, IP, financial and indemnity issues are addressed. Ensure appropriate governing law is inserted to ensure appropriate action can be taken should the need arise.</p> <p>In liaison with GCP manger ensure any milestones are viable and deliverable.</p>
10.	GCP manager	<p>Review draft contracts.</p> <p>Where appropriate Review draft contracts for adherence to GCP and the UK regulations.</p> <p>All funding milestones should be discussed with the CI, Clinical Trial Coordinator, GCP manager and Contracts Manager to ensure that unrealistic dates are not set.</p>
11.	Costing and Contracts Team	<p>Conduct final contract review and pass to Pre-Award Operations Manager for authorisation and signature.</p> <p>Once all parties have agreed terms finalise and conduct a final check of contract. Only after a final check should contracts be passed to the Operations Manager Pre Award or Director of Research Services or other designated person within the JRMO for signature.</p>
12.	Operations Manager Pre Award or Designated signatory	<p>Review, sign and date the final contract</p> <p>Pass contract back to the Costing & Contracts Team for circulation, final processing and filing.</p>
13.	Costing and Contracts Team	<p>Process fully executed copy of contract.</p> <p>Ensure all parties to the contract have signed (wet ink signature is needed for all CTIMPS) and dated.</p> <p>Ensure the effective date is completed where relevant.</p> <p>Scan contract and save on contract shared drive in JRMO and upload an electronic copy to the ReDA Documents and file hard copy in Contracts file.</p> <p>Ensure contract database is updated and CTIMP contracts excel spreadsheet is updated.</p> <p>Email a copy to the allocated JRMO Clinical Trials Monitor and Trial Coordinator.</p> <p>Please see SOP 2 Implementing an award, all contracts must be fully executed prior to</p>

		issuing Sponsor green light. Prepare and maintain contents page for all contracts in hard copy file held in JRMO.
14.	Costing and Contracts Team	Attend the Final CTIMP Meeting. Attend Final CTIMP meeting 9as arranged by the GCP manager) to ensure all external vendors are identified and clearly summarised on the Contracts Checklist.
15.	Costing and Contracts Team	Finalise the Contracts Checklist. Following the Final CTIMP meeting the Contracts Checklist should be completed fully and sent to the CI for signature. Wet ink signed copy of Contract Checklist should be filed within JRMO Sponsor oversight files. A scanned copy should be saved in ReDA Documents and the contract shared drive. Inform the GCP Manager and Governance Officer once the Contract Checklist is complete and signed by CI, and send a scanned copy.
All other studies or research projects		
16.	Principal or Chief Investigator	Notify JRMO of possible collaboration of service Contact the Joint Research Management Office (JRMO) and/or a member of the Business Development Unit (BDO) (QMUL) to inform them of possible collaboration or service.
17.	Costing and Contracts Team	Review protocol and costs at an early stage, provide PI/CI and/or BDO with Costing Questionnaire. Request copy of protocol or description of work to ensure all costs are identified at an early stage. Send a copy of the JRMO Costing Questionnaire to the CI/PI and /or BDO officer.
18.	Costing and Contracts Team	If required arrange a meeting with CI/PI to discuss further details of arrangements. Where deemed necessary and feasible arrange a meeting with the CI / PI and were applicable BDO officer to discuss the following arrangements including but not limited to: <ul style="list-style-type: none"> • Finance • IP • Governance • Contractual relationship.
19.	Costing and Contracts Team	Prepare the costing on the basis of information provided. Prepare the costing based on information provided, obtaining quotes from various service departments where applicable, ensuring relevant organisational costing methodology is utilised.
20.	Costing and Contracts Team or BDO	For new partners request a credit check. Where a new or unknown contracted partner is identified request a company credit check. Negotiations and viability will be based on the risk rating provided by the D&B credit score. The reviewing Contracts Officer and if necessary Credit Control Officer will make this assessment and both rating and assessment will documented and finance terms adjusted accordingly.
21.	Principal or Chief Investigator	Ensure the company is aware of JRMO contact. Ensure that any company representative is made aware of the JRMO point of contact for all costing and contractual negotiations or BDO officer who will liaise with the JRMO on behalf of the PI/CI.
22.	Costing and Contracts Team	Negotiate the price and terms with funder or contracted partner.

23.	Principal or Chief Investigator	Ensure that internal peer review procedures are in place.
24.	Principal or Chief Investigator or BDO	Request draft contract to be sent to the JRMO for consideration.
25.	Costing and Contracts Team	Only after a final check should contracts be passed to the Operations Manager Pre Award or Director of Research Services or other designated person within the JRMO for signature.
26.	Operations Manager Pre Award or Designated Person	Check and sign the final contract before passing back to the Costing & Contracts Team for distribution.
27.	Costing and Contracts Team	<p>Process fully executed copy of contract.</p> <p>Ensure all parties to the contract have signed and dated. Ensure the effective date is completed where relevant. Scan contract and save on contract shared drive in JRMO and upload an electronic copy to the ReDA Documents and file hard (if necessary) copy in Contracts file. Ensure contract database is updated. Email a copy to the Clinical Trials Coordinator. Please see SOP 2 Implementing an award, all contracts must be fully executed prior to issuing Sponsor green light.</p>

Change Control

This section outlines changes from version 5.0 to version 6.0 of this SOP.

Summary and description of change:
<ol style="list-style-type: none"> 1. Administrative corrections through out 2. Split into CTIMP and other research sections 3. Additions to cover non-medical and medical areas of QMUL 4. Update to JRMO checklist

List of Associated Documents

Document	Document name
1.	JRMO Contract Checklist