Joint Research Management Office Standard Operating Procedure for:			
Vendor assessments			
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Purpose:

The purpose of this standard operating procedure (SOP) is to provide guidance to ensure that any external service provider entering into an agreement with the Joint Research Management Office (JRMO) in relation to a Barts Health or Queen Mary sponsored Medicines and Healthcare products Regulatory Agency (MHR regulated research study is fit for purpose (including but not limited to skills, quality and financial viability) and able to deliver the services agreed.

Scope:

This SOP applies to all companies and service providers entering into an agreement related to any clinical trials of investigational medicinal products, clinical trials of advanced therapy investigational medicinal products, or clinical trials of non-CE marked medical devices sponsored by Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary).
Where studies are sponsored by Barts Health or Queen Mary, it is recommended Standing Financial Instructions (SFI) apply, where appropriate, to govern such agreements. This should ensure compliance with local SFI's and the Public Contracts Regulations 2015, if applicable.

For all other research, the procedures described in this SOP are viewed as best practice, however organisation procurement procedures should be followed for all services and goods For these studies, the role of the JRMO Good Clinical Practice (GCP) and Governance Manager can be performed by the JRMO Research Governance and Performance Manager, JRMO Research Management & Governance Officers or study coordinator.

Abbreviations:	
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
GCP	Good Clinical Practice
IMP	Investigational Medicinal Product
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
Queen Mary	Queen Mary, University of London
SFI	Standing Financial Instructions
SOP	Standard Operating Procedure

SOP Text:

	Responsibility	Activity
1.	Chief Investigator (CI)	**Adhere to organisational procurement policies and procedures** It is the CI's responsibility to ensure that during the vendor selection and engagement, they are aware of and comply with Queen Mary or Barts Health procurement policies and procedures and SFIs. Any purchase of goods or services must comply with the procurement procedures to ensure value for money is achieved whilst ensuring transparency and fairness and dealing with suppliers in good standing. For Queen Mary the process is outlined via the link http://qm-web.finance.qmul.ac.uk/purchasing/media/procurement/documents/procurement-pdfs/all-pdfs/How-to-Purchase-v2-July-2018.pdf For Barts Health the process is outlined via the link http://ww25.bartshealthintranet.com/About-Us/Corporate-Directorates/Finance/Procurement-and-eCommerce/Index.aspx
2.	Costing Officer	**During grant application or funding stages, identify each prospective vendor.** Work with the CI or applicant to ensure all potential vendors are identified and ensure organisation procurement procedures can be/are met. For all potential MHRA regulated studies, inform the GCP and Governance Manager and await their agreement before including vendors within a grant or funding application.
3.	Contracts Manager	**Following funding award, identify each prospective vendor and inform the GCP and Governance Manage.** Work with the CI during early engagement and the kick-off meeting to identify prospective vendors. These will be documented on the contract checklist (see *SOP 7a Costing and Contracting associated document 1*). Ensure the allocated GCP and Governance Manager is aware of all potential vendors. Allow time for the GCP and Governance Manager and CI to perform assessments prior to contract negotiations.

4.	GCP and Governance Manager	**Categorise each prospective vendor.** Assess and categorise the vendor into one of the following groups: a. **Known** service provider - a supplier which has previously passed sponsor vendor assessment within the last 5 years, where no compliance or service issues have been identified. b. **Unknown** service provider - a supplier which has not previously passed sponsor vendor assessment. c. **Preferred supplier** service provider - any company/vendor which the studies funder/Investigational medicinal product (IMP) supplier or other key stakeholder has an ongoing working relationship with and has used in the past. Preferred suppliers can be treated proportionately but a minimal vendor assessment should be performed. d. **Not approved for use:** This may be allocated to a service provider/vendor who is unable to demonstrate compliance to the applicable standards required. This could also include a supplier which has previously passed sponsor vendor assessment and been used in a study, where use has completed or been terminated, but for which service provision issues or compliance to agreed standards has not been achieved or maintained. **Note:** Service provider can be a statistician, laboratory, database provider, IMP or device manufacture or distributor, clinical trials unit (accredited/non-accredited), etc.
5.	GCP and Governance Manager	**Assess all unknown, 'Not approved for use' or preferred vendors.** Where a vendor falls into category "b - unknown" or "d – not approved for use", a vendor assessment is required. Additional assessments are not normally required for known vendors as they will have been previously assessed; however, in instances where the intended service differs from those previously provided additional assessments should be considered. **Note**: At the grant application stage a simplified assessment can be performed and used to assess basic suitability only. The main assessment will be performed at the study kick off meeting/contract negotiation stage.
6.	Contract Manager / GCP and Governance Manager	**Risk assess the use of a vendor not approved for use.** If the research team wish to use a vendor which is currently recorded as not approved for use, the Contract Manager and GCP and Governance Manager must carefully assess the risks involved in using the vendor again. This should include: • Reviewing the feedback received from previous use of the vendor. • Reviewing any identified compliance or service issues. • Conducting a more thorough vendor assessment on the particular issues identified from the previous experience.
7.	GCP and Governance Manager	**Assess service and quality.** Vendor assessment may include a combination of activities: • A questionnaire (containing agreed pertinent questions). • Assessment of CV's and previous experience. • Suitable references.

		• Referring to prior knowledge of vendors' form used in other clinical studies or research. • Assessment of quality systems and written procedures. • Conducting audits. • Review the service provided by the same vendor (as applicable). The GCP and Governance Manager should decide on how to proceed with each specific vendor assessment, this will be dependant of the service to be provided, importance of data being generated, and associated risk. The GCP and Governance manager should seek expert advice where needed. If in use, the vendor should be sent the appropriate vendor questionnaire (GCP compliance check, specific to type of vendor) to obtain an understanding of the processes and standards adhered to by the company. The level of GCP compliance check will be proportionate to the type of study and service that will be provided. For preferred suppliers the recommending party will be asked for a summary of previous history and any assessments or audits recently performed. The recommending party should also clearly state what the ongoing involvement or oversight with the vendor will be. The proportionality of further assessment will be dependent on the information provided. For any technical expert advice needed for the assessment, the GCP and Governance Manager will seek support from associated technical Barts Health or Queen Mary staff members (e.g. for IMP manufacturing or distribution, the Barts Health clinical trial pharmacist can be approached). The completed questionnaire will then be reviewed by the technical expert with the GCP and Governance Manager and Contracts Manager (if applicable) to agree whether the vendor is acceptable, or to agree any needed changes. See *associated document 1 GCP & Governance compliance sample questions*. Please note this is a guidance, specific questions must be agreed with the GCP and Governance Manager .
8.	Contracts Manager	**Assess financial viability.** The Contracts Manager will complete financial due diligence checks (This may include but not limited to Disclosure and Barring and Companies House checks) while awaiting the return of the completed questionnaire. Remind CI to comply with organisational procurement policies and procedures.
9.	GCP and Governance Manager / Costings and Contracts Team	**Conclude assessment and document assessment.** Use *Associated Document 2* to email the CI, Contracts Manager and other relevant parties a summary of the assessment and the result. If, after review, it is agreed that GCP compliance checks do not meet the standards expected for GCP and UK regulations, the JRMO will suggest procedures or changes that can be put in place but, as the sponsor, the JRMO will retain the right to decline to use or work with the company/organisation. The rational for selection or non-selection should be clear. Where there are concerns about finances of the company, the Costings and Contracts Team will advise.

		Where concerns are governance related, the GCP and Governance Manager will lead, with support as needed, from the Research Governance Operations Manager. All disagreements should be escalated to the Sponsor Oversight Group for a final decision.
10.	Contracts Manager	**Record the outcome of the financial due diligence.** Completion and comments from the outcome of the financial due diligence will be recorded on the contract's checklist (*SOP associated document 1 7 Costing and contracting*) and any associated correspondence or documentation should be retained.
11.	GCP and Governance Manager	**Agree and document vendor oversight activities.** Using the summary of assessment email and study monitoring plan the GCP and Governance Manager should plan and document how sponsor oversight will be maintained. This should be dependent on the activity and risks identified. Regular communication is the key to maintaining oversight. Oversight may include: • Formal monitoring or audits, • Face to face or telephone meetings • Regular written reports (CI or vendor)*, • Review of Trial Master File for correspondence and compliance *this can be included in the study summary reports If the vendor is a laboratory and method validation is part of the proposed work, then include oversight of validation and verification plan, including key milestones and reports to the sponsor for stop go decisions prior to analysis.

Change control

This section outlines changes from version to version

Section changed	Summary and description of changes
All	Clarification of processes
Definitions	Section removed
Relevant SOPs	Section removed in favour of hyperlinks
Appendix	Appendix email now an associated document
Feedback section	Removed in favour of addition to an EDGE workflow

List of appendices

There are no appendices.

List of associated documents

Document ref.	Document name
Associated Document 1	GCP & Governance compliance sample questions
Associated Document 2	Email template for summary and result of assessment

EDGE Database Update

EDGE ref.	
Closure workflow	Update to record vendor feedback