Standard Operating Procedures (SOP) for:			
Vendor Assessment			
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Purpose and Objective:
To ensure that any external company entering into an agreement with the Joint Research Management Office (JRMO) in relation to a research project 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, service providers or sponsors entering into an agreement related to any CTIMP (Clinical Trials of Medicinal Products), ATMP (Advanced Therapy Medicinal Products) or Clinical Trials of non-CE marked Medical Devices research project within Barts Health NHS Trust (BH) or Queen Mary University of London (QMUL). There are external vendors which have been used previously but prior to this SOP becoming effective. These historically-known vendors will be classed as 'known' and added to vendor list as and when a new project commences.

Abbreviations:	
BH	Barts Health NHS Trust
JRMO	Joint Research Management Office
HRA	Health Research Authority
NHS	National Health Service
QMUL	Queen Mary University of London
CRO	Contract Research Organization
TMF	Trial Master File
GCP	Good Clinical Practice
PI	Principal Investigator
CI	Chief Investigator
TMF	Trial Master File
CTU	Clinical Trails Unit

Relevant SOPs
This SOP is closely linked with: SOP 11a BH/QMUL Sponsorship of CTIMPs, ATMPs and Clinical Trials of non CE marked Medicinal Devices – Process for Researchers SOP 7 Costing and contracts

	Responsibility	Activity
1.	Contracts Manager	When the Contracts Manager (CM) is requested by CI to approach or becomes aware of a CI approaching an external body to request an agreement, **the CM, in conjunction with the GCP and Governance Manager should assess and categorize the external body into one of the following groups:** i. **Known** funder/sponsor/CRO/service provider ii. **Unknown** funder/sponsor/CRO/service provider iii. **Preferred supplier** CRO/service provider **'Known'** is defined as any vendor/company either historically known as acceptable (no negative feedback) to the Sponsor, or one that has been checked following the implementation of this SOP and is, from then, known to be acceptable. **'Unknown'** is defined as any vendor/company which is new to the JRMO, or any historically known vendor which has been unacceptable to the JRMO in the past, or any vendor which is deemed unacceptable following this vendor assessment (to be treated as new 'unknown' in the future). **"Preferred supplier"** is defined as any company/vendor which a funder/IMP supplier or other key stakeholder has an ongoing working relationship with, and has used in the past. **Note:** Service Provider can be, e.g. Statistician, Laboratory, Database provider, IMP or device manufacture or distributor, Clinical Trials Unit (accredited/non-accredited), etc.
2.	Contracts Manager	**Where a vendor falls into category 2 (unknown), the Contracts Manager will liaise with the Governance and GCP Managers to assess the vendor in question, before any financial due diligence check begins.**
3.	Governance and GCP Manager	**Assessing service and quality.** Governance and GCP Manager or delegated Research Management and Governance Officer to send the (unknown) vendor (e.g. sponsor or Contract Research Organisation) 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. Dependant on the information provided and the recommending party a proportionate assessment may be needed. For any technical expert advice needed for the assessment, the Governance and GCP Manager will seek support from associated technical BH or QMUL staff members (e.g. for IMP manufacturing or distribution, the BH clinical trial pharmacist can be approached). The completed questionnaire will then be reviewed by the technical expert with the Governance and GCP Manager and CM (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 GCP manager.
4.	Contracts Manager	**Assessing financial viability.** The Contracts Manager will complete financial due diligence checks while awaiting the return of the completed questionnaire.
5.	Governance and GCP Manager/ Costings and Contracts Team/ R&D Governance Operations Manager	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 JRMO, will retain the right to decline to use or work with the company/organisation. Where there are concerns about finances of the company, the Costings and Contracts Team will advise. Where concerns are governance related, the GCP Manager will lead with support, as needed, from the R&D Governance Operations Manager.
6.	Contracts Manager and Governance and GCP Manager	Completion and comments from the outcome of the financial due diligence will be recorded on the contracts checklist and any associated correspondence or documentation should be retained. A vendor will remain "known" for 5 years after the last contract. Poor service or negative comment from research teams during a study will be reviewed and assistance given as necessary and may cause a vendor to be listed as unknown.
7.	Chief Investigator/Study Team and GCP Team	Once a study (employing an external vendor) comes to an end, a member of the GCP Team should request a statement from the CI/study management team/CTU regarding their interaction and service received by the external vendor during the project. The GCP Team will then record this study team feedback in ReDA, and any negative feedback should be flagged (to be considered by the Contracts Manager and Governance and GCP Manager as appropriate).

Change Control

This section outlines changes from version 2.0 to version 3.0 of this SOP.

Summary and description of change (detail sections changed if applicable)
Section 1 : Addition of preferred supplier Section 5: SOP updated to reflect internal JRMO documents used to ensure that outcomes are documented in uniform manner.

List of Associated Documents *(these are standalone documents)*

	Document name
Associated Document 1	GCP & Governance Compliance Sample Questions