Sponsorship review proportionality

The Joint Research Management Office (JRMO) has put together this document to show the proportionality adapted for the processes and documents required when setting up the different study types (Medicines and Healthcare products Regulatory Agency (MHRA)-Regulated, Interventional and Research studies) which is reflective of study risks. The JRMO as sponsor representatives reserves the right to increase oversight on an individually study risk basis. Further step by step guidance and flow charts on the sponsorship process for each study type can be found in the sponsorship Standard Operating Procedures (SOPs) http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/

Study type	**REGULATED STUDIES** *Any study that needs to be submitted to the MHRA*	**INTERVENTIONAL STUDIES** *Research involving a change in treatment, care or other services made for the purpose of the research.*	**RESEARCH STUDIES** *Any study related to human research where no change to participant care or treatment occurs.*
Processes:			
Funding	Researchers should seek support from Costing & Contract Officer and Good Clinical Practise (GCP) & Governance Manager before submission of any funding application.	Researchers should seek support from Costing & Contract Officer before submission of any funding/grant application.	
Peer review	Independent scientific peer review & departmental authorisation as per JRMO SOP 14.	Independent scientific peer review & departmental authorisation as per JRMO SOP 14.	Independent scientific peer review & departmental authorisation as per JRMO SOP 14. Student studies may use supervisor to replace independent scientific reviews.
Face to Face Meetings	Researchers should seek support from GCP & Governance Manager prior to submission. Mandatory face-to-face Kick Off and Final Meetings.	Researchers are encouraged to meet with Governance Officer to improve overall submission feedback, processing time and avoid email overload.	
Risk assessment	Risk assessment appropriately designed for such study type is required. Performed by GCP & Governance Manager and agreed with Chief Investigator (CI) and Clinical Trials Unit (CTU), as appropriate.	Risk assessment appropriately designed for such study type is required. Completed by Governance officer.	
GCP & Governance Manager review	Joint feedback by GCP & Governance Manager and Governance officer shown in tracked	Not required, GCP & Governance Manager's advice given if needed/ requested. Governance Officer review and provide feedback shown in tracked changes.	

	changes on same document (e.g. protocol) so researcher gets one set of comments.		
Contracts	Contract checklist completed by Contracts officer. Fully executed contract must be in place before sponsorship is confirmed.	Contracts officer must confirm in writing that contract work is complete, prior to Confirmation of Sponsorship being issued.	
Researcher training	Evidence for CI and statistician (CI and lead team should ensure SOP 34a is followed). JRMO full GCP training. Or other external GCP training previously attended but attended or booked onto JRMO GCP Refresher prior to submission. Required to submit certificate of attendance as part of application.	Evidence for CI only (CI and lead team should ensure SOP 34a is followed). Have attended some JRMO training [either GCP or Good research practice at some point in the past. It is best practice to have completed a refresher every two years Or other external training attended but booked onto JRMO refresher training. If Training is detailed on the CV then no certificate is required.	
QC by Governance Team leader / Senior Governance Colleague	Mandatory by Governance team leader or delegated senior governance colleague.	No formal review – oversight and support given if required.	No formal review.
Sponsorship with conditions	Email confirmation will be issued by Governance Officer when all requirements have been met.		
Registration with public databases	Any study classified as Clinical Trial on IRAS must be registered prior to first consent. A EudraCT number is required for MHRA-regulated studies.	Any study classified as Clinical Trial on IRAS must be registered prior to first consent. Non-MHRA regulated clinical trials can be registered on SRCTN or clinicaltrials.gov.	There is no requirement to register on public database.
Confirmation of sponsorship	Confirmation of Sponsorship approval is provided once all requirements have been met.		
Documents:			
Protocol	Use of the JRMO MHRA Regulated Study protocol template is mandatory unless using CTU agreed template or under exceptional circumstances.	Use of the JRMO Interventional Studies protocol template is mandatory unless using CTU agreed template or under exceptional circumstances.	Use of the JRMO Research Studies protocol template is mandatory unless using CTU agreed template or under exceptional circumstances.
CV	CI and statistician. Electronically signed and dated within 2 years. This should be on HRA	CI only. Electronically signed and dated.	CI only.CV does not need to be signed or dated as long as it is

	template or max 2 pages and details relevant publications, qualifications, role within previous studies and any relevant experience and training.		*current* and *updated* with latest studies / publications.
IRAS form	Required.		Required (except where study is NHS REC and HRA exempt e.g. QMERC application only).
CI-Sponsor Agreement (previously known as Conditions of Sponsorship)	Agreement appropriately designed for such study type to be submitted with sponsorship application. CI wet ink signature is required.	Agreement appropriately designed for such study types to be submitted with sponsorship application. CI electronic signature will be accepted if CI emails or copied in email.	
Key Collaborators (named in A63 of IRAS)	CV and GCP certificate not required.		
SoECAT/OID/ Site Agreements/contract	Site Agreement/Contract is required (unless single centre Barts Health sponsored study).	Site Agreement/Contract is required for the first 4 IRAS categories. Organisation Information Document (OID) and Schedule of Events Cost Attribution Template (SoECAT) are required (unless single centre Barts Health sponsored study).	
PIS / ICF + any other participant-facing documents	Mandatory for all studies as appropriate for study design. Templates for PIS / ICF can be found on http://www.hra-decisiontools.org.uk/consent/examples.html		
Statistics / Data Collection Method	As designed in study protocol. System validation document and CRF required.	As designed in study protocol.	