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 if required. Further step by step guidance 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 Practice (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	Both reviewers must be independent of the work proposed - and also independent of the sponsor organisation (not employed by the sponsor when this is Barts Health or Queen Mary). See SOP 14 Peer Review for further details.	Both reviewers should be independent of the work proposed, however for educational projects, the internal reviewer can be the supervisor. - Ideally both reviewers should be independent of the sponsor organisation; however one external and one internal reviewer also acceptable. See SOP 14 Peer Review for further details.	Both reviewers can be internal (employed by the sponsor organisation), one of which can be a student's supervisor (educational studies only); one of which must be independent of the work proposed. See SOP 14 Peer Review for further details.
Face to Face Meetings	Researchers should seek support from GCP & Governance Manager prior to submission. Early engagement meeting is optional and	Researchers are encouraged to meet with RMGO to improve overall submission feedback, processing time and avoid email overload.	

	encouraged. Mandatory meetings are Kick Off and Final governance Meetings.		
Risk assessment	Risk assessment appropriately designed for such study type is required. Performed by GCP & Governance Manager and agreed with Chief Investigator (CI),Clinical Trials Unit (CTU) and sponsor representative, as appropriate.	Risk assessment appropriately designed for such study type is required. These will be completed by Governance officer , any moderate risk studies will be discussed with governance manager.	Lower risk research studies may not require a risk assessment. See SOP 23 Associated Document Triaging for Research Study Risk Assessment for further details.
GCP & Governance Manager review	Joint feedback by GCP & Governance Manager and Governance officer shown in tracked changes on same document (e.g. protocol) so researcher gets one set of comments.	Not required, GCP & Governance Manager's advice given if needed/ requested. RMGO review and provide feedback.	
Contracts	Contract checklist completed by Contracts officer and must be signed by the CI. 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 and lead team in accordance with SOP 34a Researcher Training.	

QC by Governance Team leader / Senior Governance Colleague	Mandatory by Research Governance and Performance Manager or delegated senior RMGO.	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 CTIS number is required for MHRA-regulated studies.	First 4 IRAS category studies must be registered on a public data base such as ISRCTN or clinicaltrials.gov prior to first consent.	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, ideally using the HRA template or max 2 pages and details relevant publications, qualifications, role within previous studies and any relevant experience and training.	CI only. Electronically signed and dated.	CI only. CV does not need to be signed or dated as long as it is current and updated with latest studies/publications.
IRAS form	Required. Combined review IRAS required for CTIMPs. Medical devices should continue using usual IRAS platform.		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. Digital or wet ink CI signature are required. Cut and paste signatures are not accepted.	Agreement appropriately designed for such study types to be submitted with sponsorship application. CI digital or wet ink signature will be accepted if CI emails or copied in email. Cut and paste signatures are not accepted.
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.