# Sponsorship review guidance document for Interventional and Research

**Studies.**http://www.jrmo.org.uk/performing-research/conducting-research-in-the-nhs/setting-up-a-study/a-whole-new-study/

**Sponsor:**

When Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) agree to sponsor a research study, they are accepting considerable legal and regulatory responsibilities and organisational risks.

Good Clinical Practice (GCP) E6 R2 defines sponsor as: An individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.

The Health Research Authority (HRA) sets out guidance on the expectations of sponsors. This includes that sponsors should satisfy themselves that the study meets the relevant standards and that arrangements are put and kept in place for:

- Management.
- Appropriate peer review.
- Governance Sponsorship Review; Completed by JRMO team only
- All supporting information being supplied to the regulators for their consideration.
- Defining roles and responsibilities for the duration of the study.
- Monitoring and audit.
- Risk assessment processes.
- Public and participant involvement in the study.
- Ensuring the training and suitability of the research team.
- Public registration of the study; Clinicaltrials.gov/ International Standard Randomised Controlled Trial Number (ISRCTN) guidance document
- Dissemination of the results.
- Study oversight.
- Guidance for academic supervisors.
- Providing on-going quality assurance.
- Providing insurance or indemnity for liabilities of the sponsor and investigator

The sponsor of the study is usually the substantive employer of the CI. For student projects, it is usually the academic institution. Barts Health cannot sponsor international research so when the study involves international sites, the sponsor must be Queen Mary. There are some situations where sponsoring organisation may not be clear, please liaise with team leader.

**Research Studies:**

Research studies are those that are related to human research where no physical intervention is occurring.

If a study involves apps, software, decision making tools, devices or drugs and it is not clear if it is approved/validated and used within its licence, please escalate study to GCP manager for advice.

Examples:

Study involving questionnaires on patients thoughts after surgery (no change to patient care)

Study involving taking extra blood sample at time of standard of care blood tests for analysis which will not change patient care

Study involving analysing data from patients that attended emergency department in 2019

**Interventional studies:**

Research involving a change in treatment, care or other services made for the purpose of the research.

Examples:

Study involving taking extra blood sample and MRI scan which will determine the drug and dose administered to patient.

A randomised trial using 2 different UKCA/CE marked device within its intended purpose to assess the different outcomes of the devices

**Valid submission:**

Valid submission: This submission should include all documents that will be reviewed by the Health Research Authority (HRA) and Research Ethics Committee (REC)/ Confidentiality Advisory Group (CAG)* or other regulatory body, and the forms should be received in parallel so that the JRMO can review the consistency across all documents.

*Studies requiring CAG approval, the appropriate Caldicott Guardian will need to sign off the IRAS form appropriately. Contact with the CAT (Confidentiality Advisory Team) will also needs to be made and the application submitted within 24 hours, otherwise the submission is deemed invalid and will be cancelled by CAG .

For each study type, the requirements for valid submission are on the submission checklist.

**Chief and Principal Investigator:**

For Barts Health/Queen Mary *single site* sponsored studies the CI should be the Barts Health site's Principal Investigator (PI). For researchers outside Barts Health/Queen Mary organisations who want to acquire sponsorship from Barts Health / Queen Mary, the funding needs to be awarded to Queen Mary/Barts Health as a minimum for the sponsorship request to be considered. For further details please see the JRMO Policies

The HRA and UK policy framework for health and social care research define the CI as: An individual who is responsible for the conduct of the whole study and is the overall lead researcher for a research study. The named CI should be a researcher who is professionally based in the UK, as they will be:

- Able to supervise the research effectively
- Readily available to communicate with the REC and other review bodies during the application process and where necessary during the conduct of the research.

For research studies, the CI does not need to be medically qualified (as the study doesn't involve any change to participant care) but the area of expertise should be appropriate.

For new CI's, ensure qualifications, training and area of expertise are appropriate. New CI's should have research experienced supervisors supporting them

Students Studies
Students should not normally take the role of CI at any level of study, as this function should be undertaken by supervisors or course leaders. Exception is made for an experienced care practitioner or manager undertaking an educational qualification for continuing professional development or a doctoral-level study while employed by a health or social care provider or a university, or for a researcher undertaking a doctoral-level study in receipt of a fellowship.

Although non-doctoral students should not be named as the CI, it is expected that the student will complete the application form on behalf of the CI as part of their training. The REC will invite the student to attend the meeting to answer questions about the study and will address all correspondence to the student (copied to the CI). Supervisors are also encouraged to attend the meeting. If a favourable opinion is given by the REC, it is expected that the student will undertake the research under the supervision by the CI.

HRA student studies- more details can be found via https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/

## Other study types and guidance

**QMERC and Governance Sponsorship Dual review:**
Some studies may require dual review by both the QMERC and governance teams. Ensure early communication and conversations are occurring between QMERC and Governance teams and all conversations and decisions are filed accordingly. If a possible dual review is identified it should be notified to Senior REF/Senior GO and they should liaise (calling on assistance from Research Support & Development Manager & Research Governance Team Leader where required). A meeting should take place internally to establish the appropriate approval routes, with joint meeting held with the researcher(s) either before (to gather information) or after (to inform of the application and approval routes) and to provide clarity.

The criteria that determine whether a study requires dual review are outlined below:

- non-NHS research with a heightened risk to the institution and/or participant;
- novel or invasive research intervention;
- the need for additional indemnity and sponsorship or to ensure regulatory compliance
- a purely healthy volunteer study that has a medical or health focus
- a multi-arm study where the investigator chooses to get separate approvals for different arms (e.g. a healthy volunteer element could be covered by QM Ethics and future NHS elements covered by a separate NHS REC/Sponsorship application). E.g. work package 1 and 2 where 1 falls under QMERC and is required to be conducted before NHS elements are added to the study in work package 2. Governance will then conduct sponsorship review on NHS elements once added.

Early communication and engagement with both QMERC and Governance teams is recommended to aid efficient approvals.

**Retrospective data studies**: follow associated document 2

**Research Tissue Banks: 5 year ethics renewal**

*Please note, it is advised that applications are submitted at least 3 months prior to the REC expiry date.*

EDGE: add each renewal to the existing EDGE project. Keep the original IRAS number and add the latest IRAS number under additional IRAS number. Ensure study information and milestones are correct. Add note in note tab detailing the ethics renewal and new IRAS/REC references.

Review process:

- Review all amended study documents and updated protocol – ensure compliance with current sponsor/regulatory requirements
- Updated scientific peer review is only required if original protocol/procedures have changed substantially
- Designated individual/tissue bank manager – obtain reconfirmation of approval
- Clinical director approval – obtain reconfirmation of approval
- Support department – obtain reconfirmation of approval
- Preaward team – ensure funds are sufficient for renewal and obtain signed 'No funding form' if there are no changes to funding
- Issue sponsorship with conditions once all of the above are complete
- After regulatory approvals are issued, obtain final document set and issue confirmation of Sponsorship
- Update EDGE data information and upload documents to EDGE files
- Capacity and capability reconfirmation not required.

**Governance Review:**

It is advisable to arrange meeting with CI/CI delegate to discuss study, to seek clarifications and to build professional relationship. Other sections of JRMO or support departments should be involved in the review of study sponsorship if necessary (SOP 12b Associated Document 3 Early engagement meeting tool).

| | |
|---|---|
| IRAS form | Check consistency with Protocol and use below as guidance for ensuring the IRAS form is completed correctly.<br>Review and asses chosen IRAS category<br>http://www.jrmo.org.uk/performing-research/conducting-research-in-the-nhs/setting-up-a-study/iras-form-guidance/<br>https://www.myresearchproject.org.uk/help/hlpcollatedqsg-iras.aspx#743<br>Give feedback as comments on the IRAS or as a list specifying each IRAS question<br>For studies that may be adopted on NIHR portfolio, advise CI to select 'yes' to question 5b of the IRAS study Filter. |
| Research Protocol | Protocol should be on relevant JRMO template and signed once finalised.<br>Check consistency between protocol and IRAS form, particularly:<br>- Study titles<br>- IRAS A5-1 – protocol version and date<br>- A10/A11 – research objectives<br>- A13 – design and methodology<br>- A17-1 and A17-2 – inclusion and exclusion criteria<br>- A18 – interventions<br>- A43, A44, A45 – archiving<br>- A59 – sample size<br>- A65 – funding<br>- A69-1 – study duration<br>- A78 – If it could lead to intellectual property rights – liaise with Gerry Collins |

| | |
|---|---|
| | Provide feedback as tracked changes and comments<br>Add IRAS number, version, date and page number to the footer. Version and date must be consistent on document title and document footer. |
| Sponsor CI agreement | Ensure completed fully and table has been reviewed. Must be signed by CI electronically |
| Participant information sheet(s) (PIS) (Where applicable) | PIS should be written in lay form so the patients are aware exactly what they will be involved in e.g. how many mls of blood will be taken, how many visits are required, what an MRI scan involves etc. Ensure HRA GDPR wording has been added with correct sponsor DPO contact, research team details and site PALS details (can be left blank for localisation).<br>Ensure the PIS is age and audience appropriate e.g. paediatric studies will have different PIS for different age groups, separate PIS for parents/carers/nominated individuals.<br>Add IRAS number, version, date, page number to the footer. Version and date must be consistent on document title and footer of document |
| Consent form(s) (Where applicable) | Check all relevant points have been added from HRA consent form template. The consent form should have the correct points of consent and should be age appropriate e.g. paediatric studies will have different consent for different age groups. If consent is being taken by parents or nominated individuals, then ensure assent and consent forms are submitted.<br>Add IRAS number, version, date, page number to the footer. Version and date must be consistent on document title and footer of document |
| Other study documents e.g. GP letter, non-validated questionnaires, topic guides, dairies etc | Add IRAS number, version, date, page number to the footer. Version and date must be consistent on document title and footer of document<br>Ensure information in these documents are consistent with the protocol, IRAS and other study documents. |
| HRA OID<br><br>And<br><br>HRA SoECAT | Not applicable for Barts Health sponsored studies with only Barts health as a site. This must be completed for Queen Mary sponsored studies with Barts Health as a site. All multi-site studies will need this completing.<br><br>Send SoECAT to preaward/Acord team. Schedule of Events needed for studies with no funding/costs which should be sent to preaward team for review.<br><br>OID – for governance team to review and sign the sponsor section. Check all appendices are completed before sending for site signature (Barts pre-award sign the site signature if Barts is a site). If study is CTIMP, device or IRAS first 4 categories then mNCA will replace the OID and 'separate site agreement' should be selected for appendix 1 on OID. |
| Sponsor Data DPIA pre-screening form (including evidence of submission to the DPIA/IG team) | See SOP 16a Data protection for full details, procedure, and pre-screening form. Forms should be submitted to: bartshealth.infogov@nhs.net or data-protection@qmul.ac.uk by the researcher (depending on sponsor) |
| Scientific peer review | Please follow SOP 14. Ideally external and independent review of the protocol. If external funding awarded this is accepted. If funder is AMRC member, review evidence doesn't need to be supplied https://www.amrc.org.uk/pages/category/member-directory?Take=20<br><br>If peer review evidence has been submitted, please ensure change suggestions is evident or evidence of correspondence with reviewer is supplied |

| | |
|---|---|
| Departmental authorisation | Please follow SOP 14. Letter/email authorisation of appropriate person within the department in which the research will take place. |
| Costings and Contracts | Queen Mary : liaise with Queen Mary preaward team jrmo-helpdesk-preaward@qmul.ac.uk to confirm costing and contract review. Add worktribe number to EDGE and ensure project is live before proceeding. For studies with Barts site, Barts preaward will sign site agreement/OID and agree SoECAT/SoE for site<br><br>Barts Health: liaise with Barts preaward team jrmo-bartshealth@qmul.ac.uk to confirm costing and contract review. |
| Approval for Non-Funded Projects (New Studies) Form | Only complete where you may think there are no costs associated with setting up and delivering the study. Form available at: http://www.jrmo.org.uk/about-us/standard-operating-procedures-sops/jrmo-only-sops/ |
| Curriculum Vitae | Chief Investigator signed and dated within 2 years. For student projects, CV of student must also be provided |
| Evidence of training | GCP required for CI dated within 3 years. CI needs to 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. Other external training e.g. NIHR acceptable but CI to be booked onto JRMO refresher training. |
| Validated questionnaire | All validated questionnaires must be provided and also uploaded to IRAS. Evidence of the copyright |
| Supporting departments: Pathology, Pharmacy, Imaging, Radiology | Check IRAS and protocol for any involvement of blood tests, imaging scans, IMP, including standard of care. Obtain approval from Barts support department teams: *check list of supporting department contact in shared drive*<br>If the bloods are being processed in Queen Mary lab, then approval from lab manager is sufficient. Ensure the OID or an MTA is in place to cover the movement of samples if necessary.<br><br>Radiology department will also need to review and sign the ARSAC PRA form created in IRAS. Sign off from Clinical Research Expert (CRE) and Medical Physics Expert (MPE) is also required ( Part B, section 3 of IRAS ). |
| Risk assessment and Queen Mary insurance | When reviewing the research project, consider:<br>- Compliance with SOP38c<br>- Compliance with ICH-GCP and UK policy framework<br>- Conflict of interest on IRAS form declared<br>- CI and team: consider CI's area of expertise and supporting coordination team<br>- Database location: for PID; Queen Mary safe haven or Barts Health based<br><br>For research studies, a risk assessment does not need to be conducted unless:<br>- QA manager/auditor flag previous audit/non-compliance history and deem a risk assessment is necessary<br><br>If the trial involves any of the below points, the protocol. Informed consent form will need to be referred to Queen Mary insurance brokers for review:<br>- Clinical trials or other intervention studies that aim to enrol pregnant women<br>- Clinical trials or other intervention studies where participant is under |

| | |
|---|---|
| | the age of 5 years at point of entry into the study<br>- Clinical trials or other intervention studies with international sites (N.B. this may incur additional costs)<br>- Interventional studies with a target of >5K participants<br>- COVID trials<br>- Therapies targeting the brain, blood-brain barrier or cerebrospinal fluid<br>- Cell/ gene therapy, including gene editing<br><br>If any of the above triggers are identified:<br>- For Queen Mary sponsored studies, send the protocol to Queen Mary insurance broker for approval<br>- For both Queen Mary/Barts Health sponsored studies conduct risk assessment as per SOP23. |
| Capacity and capability | For sponsored studies with Barts Health as a participating site, conduct sponsorship and C&C review together:<br>- Clinical director approval<br>- CV and GCP for local study team (Best Practice GCP dated within 2 years)<br>- Research passports/letters of access if needed<br>- Site specific recruitment targets<br>- Site level approval for support departments |