**Joint Research Management Office Document submission checklist (Interventional studies)**

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| **Chief Investigator (CI)** |  | **Sponsor** |  |
| **Study Title** |  | **Integrated Research Application System (IRAS) ID** |  |
| **EDGE Number *(if known)*** |  | **Worktribe number *(if applicable)*** |  |
| **Governance Officer *(if known)*** |  | **Costing officer *(if known)*** |  |
| **Applying for portfolio eligibility?**  | Please select ‘yes’ for IRAS 5(b) | **Speciality**  |  |
| **Division** |  |
| **Will Barts Health NHS Trust (Barts Health) be a site?** | If yes, specify locations: | **External vendors or collaborators** |  |

All documents listed below as “essential” are part of the “valid” document set – valid document set must be submitted to research.governance@qmul.ac.uk for the governance review to start, other documents listed as “where applicable” or “essential but can be supplied during review” maybe provided during the governance review. Further guidance on the items listed can be found at the end of this document.

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| **Document (\*see guidance)** |  | **Tick if included in submission** | **Comment (If not applicable then please state reason)** |
| IRAS form  | *Essential* | ☐ |  |
| Sponsor to CI sponsorship agreement  | *Essential* | ☐ |  |
| Research Protocol  | *Essential* | ☐ |  |
| Participant Information Sheet(s) PIS) | *Essential* | ☐ |  |
| Consent form(s) | *Essential* | ☐ |  |
| Health Research Authority (HRA) Organisation Information Document (OID) | *Essential\** | ☐ | *\*Not applicable for Barts Health sponsored studies with only Barts health as a site.* |
| HRA Schedule of events cost attribution template (SoECAT) | *Essential\** | ☐ | *\*Not applicable for Barts Health sponsored studies with only Barts health as a site.*[*https://www.nihr.ac.uk/documents/etc-soecat-guidance/11483*](https://www.nihr.ac.uk/documents/etc-soecat-guidance/11483) |
| Joint Research Management Office (JRMO)-completed costings | *Essential* | ☐ | *Only supply with WorkTribe number.**If using existing money, then provide PI account number and breakdown of costs based on protocol.*  |
| Scientific peer review | *Essential* | ☐ |  |
| Sponsor Data Protection Impact Assessment (DPIA) pre-screening form ( including evidence of submission to the DPIA/IG team) | *Essential*  | ☐ |  |
| Departmental Authorisation | *Essential but can be supplied during review* | ☐ |  |
| Public database registration ( Clinicaltrials.gov/ISRCTN ) | *Essential but can be supplied during review* | ☐ | *Please provide registration number**( Only applicable for IRAS 2nd, 3rd, and 4th Category**IRAS 1st category is for EudraCT registration only )* |
| Curriculum Vitae of CI  | *Essential but can be supplied during review* | ☐ |  |
| Evidence of training for CI  | *Essential but can be supplied during review* | ☐ |  |
| Site Agreements | *Where applicable*  | ☐ | *Site agreements are only applicable for the first 4 IRAS categories* |
| Funding/Award letter | *Where applicable* | ☐ |  |
| Vendor Agreement | *Where Applicable* | ☐ |  |
| Material Transfer Agreement/Data Transfer Agreements | *Where applicable* | ☐ |  |
| Validated questionnaire | *Where applicable* | ☐ |  |
| Non-validated questionnaire | *Where applicable* | ☐ |  |
| Interview topic guides | *Where applicable* | ☐ |  |
| Letters/emails of invitation to participants | *Where applicable* | ☐ |  |
| Letters and/or information sheets for GP/consultant | *Where applicable* | ☐ |  |
| Advertising material | *Where applicable* | ☐ |  |
| Radiology/Pathology/Pharmacy/ Medical/Clinical Physics approval /Medical illustration/ Lung Function  | *Where applicable* | ☐ | *Confirm which has been requested/approval received for.* |
| Evidence of appropriate translation | *See guidance* | ☐ |  |
| Any other study-specific documents or other regulatory approvals as identified on IRAS Form | *Where applicable* |  |  |

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| **Document (\*see guidance)** |  | **Tick if included in submission** | **Comment***Please list* |
| **Device section:** *List Equipment/Devices to be used* |
| Name | For clinical use | With CE mark indication | Is item loaned/ gifted?*\*If loaned or gifted is the item MIA registered?* |
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**Guidance**

**All documents that will be submitted to the REC and HRA should be submitted. All documents should be submitted in word format (editable format) and in draft form.**

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| IRAS form | Main application form that constitutes application to regulatory bodies found here: <https://www.myresearchproject.org.uk/>. To be submitted for sponsorship in draft PDF.Further guidance- <http://www.jrmo.org.uk/performing-research/conducting-medical-research/setting-up-a-study/iras-form-guidance/> |
| Conditions of Sponsorship | Available at: <http://www.jrmo.org.uk/about-us/standard-operating-procedures-sops/jrmo-only-sops/> as Associated documents for both SOP 12a and SOP12b.  |
| Research Protocol | On relevant JRMO template. See <http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/> for templates. This is mandatory and should have a date and version number.  |
| PIS | Where applicable. For all that involve prospectively recruiting patients or healthy volunteers. HRA guidance available at <http://www.hra-decisiontools.org.uk/consent/> *If a multisite study, please submit without local headers so it can be adapted at each site. For single site, the documents should be localised to site.* |
| Consent form(s) | Where applicable. For all that involve prospectively recruiting and consenting patients or healthy volunteers. HRA guidance available at <http://www.hra-decisiontools.org.uk/consent/> *If a multisite study, please submit without local headers so it can be adapted at each site. For single site, the documents should be localised to site.* |
| HRA OID/Site AgreementsAndHRA 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.Guidance and documents can be access via - <https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-OID> |
| Sponsor Data Protection Impact Assessment (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 prior to submission to the JRMO. Both the form and submitting email should be part of this submission to the JRMO. Please allow sufficient time for the DPIA/IG team to response  |
| Scientific peer review | Please follow SOP 14. Ideally external and independent review of the protocol. Supervisor review accepted for educational research. If external funding awarded this is accepted. Please include evidence that you have reviewed and implemented change suggestions or evidence of correspondence with reviewer to justify why not.  |
| 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 | If you wish to discuss a study budget, please contact the JRMO- jrmo-helpdesk-preaward@qmul.ac.uk. If there are no costs a ‘No Cost Declaration Form’ is to be completed. Form available at: <http://www.jrmo.org.uk/about-us/standard-operating-procedures-sops/jrmo-only-sops/> as Associated documents 7 for both SOP 12a and SOP13a. For Queen Mary University of London researchers only: Please see following link to the online costing questionnaire: <https://webapps2.is.qmul.ac.uk/ecosting/>  |
| Curriculum Vitae  | CI signed and dated.  |
| Evidence of training | GCP or equivalent training. To book please see: <http://www.jrmo.org.uk/news-and-training/training/> |
| Validated questionnaire | Evidence of the copyright |
| Radiology approval | Please contact: salma.abdullahi3@nhs.net & claudio.melchiorri@nhs.net. To initiate the local imaging review please forward the following: IRAS, Protocol, PIS, and Imaging Manual (if available) |
| Pathology approval  | Needed when there is Pathology involvement in protocol. Please contact: aisha.hassan1@nhs.net & claudio.melchiorri@nhs.net.  For Point of Care Testing (POCT) device studies : There is a Barts Health POCT Committee which reviews documentation and confirm whether an application to this committee is required or not. Dr Anne Dawnay (anne.dawnay@nhs.net) is the chair of this POCT Committee who confirms if an application to the committee is required. Pathology clinical leads are made aware of these studies in case they have any issues to raise as well. |
| Pharmacy approval | For local pharmacy involvement, pharmacy must be informed as early as possible via rlhpharmacyct.bartshealth@nhs.net & stuart.chandler@nhs.net & claudio.melchiorri@nhs.net. . Please be mindful that pharmacy sponsor review is separate to site review so pharmacy will not start the local site review until you bring it to their attention. |
| Medical / Clinical Physics approval | Needed for all devices and equipment that are the focal point of the study. Please contact research.clinicalphysics@nhs.net copying in allan.wilkins@nhs.net and Gursharan.Kalsi@nhs.net POCT device studies are reviewed by Pathology. |
| Medical illustration  | For Bart Health NHS Trust and where there’s medical photography involved, please liaise with Bob Tapper ( bob.tapper@nhs.net)  or Darrin Hawkins (darrin.hawkins@nhs.net) to gain approval and medical illustration costs for the study. For Whipps Cross and Newham medical photography please email medicalphotography.wx@nhs.net.  |
| Lung function testing | Please contact paul.pfeffer1@nhs.net and andy.stubbington1@nhs.net where there is a requirement for lung function testing at Barts Health.  |
| Evidence of appropriate translation | It may be necessary to translate some of your study documents in order to open the study in other countries, or to recruit participant groups who do not speak English. Translated documents must be accompanied by:* A translation certificate or other suitable evidence from the organisation completing the translation.
* Back-translation evidencing that the meaning of the text has not changed.

Any translated materials that will be given to participants must also be submitted to, and approved by, the REC.The study team should discuss the proposed method of translation with the JRMO to confirm its suitability. |