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| --- | --- |
| **Principal Investigator/Local Collaborator** |  |
| **Study Title**  |  | **IRAS number** |  |
| **Work tribe number***if applicable* |  |
| **Costing officer** |  |
| **Sponsor** |  | **Speciality**  |  |
| **Which Barts Health NHS Trust hospital will be a site? Confirm recruitment target for each site** |  |

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| **Document *(\*see guidance)*** |  | **Tick if included in submission** | **Comment/Reason** |
| HRA initial assessment letter  | *Essential* *if applicable* | [ ]  |  |
| HRA approval letter | *Essential* |[ ]   |
| REC favourable opinion letter | *Essential**if applicable* |[ ]   |
| MHRA letter of no objection | *Essential* *if applicable* |[ ]   |
| Confidentiality Advisory Group approval letter | *Essential* *if applicable* | ☐ |  |
| Clinical Board/Departmental authorisation | *Essential* |[ ]   |
| Local PI confirmation email | *Essential* |[ ]   |
| Curriculum Vitae of study team | *Essential* |[ ]   |
| Researcher Training certificate (GCP certificates of study team) | *Essential* |[ ]   |
| Organisation Information Document  | *Essential**if applicable* |[ ]   |
| HRA Schedule of Events/SoECAT | *Essential*  |[ ]   |
| Costings/Contract/budget/contract  | *Essential* *if applicable*  |[ ]   |
| Letter of Access (LoA) / Research Passport  | *Essential* *if applicable*  |[ ]   |
| Non-NHS SSI form  | *Essential* *if applicable*  |[ ]   |
| Radiology approval | *Essential**if applicable*  |[ ]   |
| Pathology approval  | *Essential* *if applicable*  |[ ]   |
| Pharmacy approval | *Essential* *if applicable*  |[ ]   |
| Medical / Clinical Physics approval | *Essential* *if applicable*  |[ ]   |
| Lung Function | *Essential* *if applicable*  |[ ]   |
| Any other study-specific documents or other regulatory approvals as identified on IRAS Form |[ ]   |
| **Device section:** *List Equipment/Devices to be used* |
| Name | For clinical use | With CE mark indication | Is item loaned/ gifted?*\*If loaned of gifted is the item MIA registered purchased* |
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Study submission documents should be sent to Research.Governance@qmul.ac.uk who will also be able to help with questions and queries

**\*Guidance**

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| Regulatory approved study documents  | For non-CTIMPs final document set approved by the HRA as per Appendix A - List of Documents e.g. localised protocol, IRAS, PIS, and ICF etc. For CTIMPS we require REC, HRA and MHRA approved final document sets  |
| Clinical Board/Departmental authorisation | Letter/email authorisation of appropriate person within the department in which the research will take place  |
| Local PI confirmation email | Confirmation email from PI confirming that he/she is happy to participate in study |
| Curriculum Vitae  | CV for Principal Investigator and all study team members who will be involved on the study, signed and dated within the last two year |
| Researcher Training certificate | GCP or RGF training for Principal Investigator and all study team members who will be involved on the study, issued within the last two years.  |
| Letter of Access (LoA) / Research Passport | Required for members of the research team who do not have existing contracts in place but conducting research activities at Bart’s Health NHS Trust.Please contact research.governance@qmul.ac.uk to obtain Letter of Access (LoA) or Research Passport. |
| SoECAT | To be approved by JRMO Costing and Contracts team. Please contact: jrmo-bartshealth@qmul.ac.uk  |
| Costings and Contract  | Liaise with JRMO Costing and Contracts team jrmo-bartshealth@qmul.ac.uk to ensure appropriate contracts are in place. If there are no costs a ‘No Cost Declaration Form’ is to be completed.  |
| Radiology approval | Needed when imaging is performed within the protocol. Please contact: bartshealth.researchimaging@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: [bartshealth.ResearchPathology@nhs.net](file:///C%3A/Users/hmw844/OneDrive%20-%20Queen%20Mary%2C%20University%20of%20London/Desktop/bartshealth.ResearchPathology%40nhs.net)  |
| Pharmacy approval | Needed when there is Pharmacy involvement in protocol. Please contact: bartshealth.ctpharmacy@nhs.net& stuart.chandler@nhs.net  |
| Medical / Clinical Physics approval | Needed for all devices and equipment that are the focal point of the study. Please contact: research.clinicalphysics@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.  |
| Ophthalmology Approval | Please contact anu.sharma5@nhs.net for any eye tests happening in the research study |
| POCT Approval | Please contact pointofcaretrlh.bartshealth@nhs.net for any pregnancy testing happening in the research study |
| Cardiac Imaging | Please contact guy.lloyd1@nhs.net for any specific cardiac imaging happening in the research study |
| Other documents  | If study involves the collection, storage and use of tissue please liaise with The Human Tissue Resource Centre (HTRC) <http://www.jrmo.org.uk/performing-research/research-facilities/clinical-facilities/htrc/what-is-the-htrc/> and obtain approval. |