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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* |
|  |  |  | |  |

Study submission documents should be sent to [Research.Governance@qmul.ac.uk](mailto: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](mailto:jrmo-bartshealth@qmul.ac.uk) |
| Costings and Contract | Liaise with JRMO Costing and Contracts team [jrmo-bartshealth@qmul.ac.uk](mailto: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](mailto: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:/Users/hmw844/OneDrive%20-%20Queen%20Mary,%20University%20of%20London/Desktop/bartshealth.ResearchPathology@nhs.net) |
| Pharmacy approval | Needed when there is Pharmacy involvement in protocol.  Please contact: [bartshealth.ctpharmacy@nhs.net](mailto:bartshealth.ctpharmacy@nhs.net)& [stuart.chandler@nhs.net](mailto: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](mailto:research.clinicalphysics@nhs.net) |
| Lung function testing | Please contact [paul.pfeffer1@nhs.net](mailto:paul.pfeffer1@nhs.net) and [andy.stubbington1@nhs.net](mailto:andy.stubbington1@nhs.net) where there is a requirement for lung function testing at Barts Health. |
| Ophthalmology Approval | Please contact [anu.sharma5@nhs.net](mailto:anu.sharma5@nhs.net) for any eye tests happening in the research study |
| POCT Approval | Please contact [pointofcaretrlh.bartshealth@nhs.net](mailto:pointofcaretrlh.bartshealth@nhs.net) for any pregnancy testing happening in the research study |
| Cardiac Imaging | Please contact [guy.lloyd1@nhs.net](mailto: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. |