**Joint Research Management Office document submission checklist**

**(Medicines and Healthcare products Regulatory Agency regulated studies)**

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| --- | --- | --- | --- | --- |
| **Chief Investigator (CI)** |  | | | |
| **Study Title** |  | Integrated Research Application System (IRAS) number: | | |
| **Sponsor** |  | **On National Institute for Health Research (NIHR) Portfolio?** | | **Y/N/Applied and pending approval** |
| **EDGE Number** |  | Work tribe number: |  | |
| **ReDA Number** |  | Costings Officer |  | |
| **Speciality** |  | Division |  | |
| **Will Barts Health NHS Trust (Barts Health) be a site?** | Yes/No If Yes specify locations | | | |
| **Have you discussed with Governance team?** | Yes/No | If yes Insert name | | |
| **Have you discussed with Good Clinical Practice (GCP) team?** | Yes/No | If yes Insert name | | |
| **External vendors or collaborators:** | *Please list:* | | | |

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| --- | --- | --- | --- | --- |
| **Document** | **Essential** | **Included in submission**  **Y/N** | **Comment** | |
| IRAS form | Essential |  | *Please list* | |
| Sponsor to CI Agreement | Essential |  | *Please list* | |
| Cover letter to Research Ethics Council (REC) | Essential |  |  | |
| IRAS Clinical Trial Authorisation (CTA) | Essential |  |  | |
| Covering letter to the Medicines and Healthcare products Regulatory Agency (MHRA) | Essential |  |  | |
| EudraCT or public database registration email | Essential |  | *Please provide registration number* | |
| Research protocol (signed) | Essential |  |  | |
| Participant Information Sheet(s) (PIS) | Essential |  |  | |
| Consent form(s) | Essential |  |  | |
| Risk Assessment form | Essential |  | *The study team are to fill in the first column of the risk assessment forms before the kick off meeting*. | |
| Scientific peer review | Essential |  |  | |
| Departmental authorisation | Essential but can be supplied during review |  |  | |
| Letter from statistician  (or agreed equivalent) | Essential |  |  | |
| Joint Research Management Office (JRMO)-completed costings | Yes |  | |  | | --- | | *Only supply with worktribe number.* |   *If using existing money then provide PI account number and breakdown of costs based on protocol.* | |
| Funding / Award letter | Essential |  |  | |
| Curriculum Vitae of CI and statistician | Essential |  |  | |
| Evidence of GCP training for CI and statistician | Essential |  |  | |
| Health Research Authority (HRA) Organisation In formation Document | Essential |  | |  | | --- | | *\*Not applicable for Barts Health sponsored studies with only Barts health as a site.* | | |
| HRA 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* | |
| Vendor agreement | If applicable |  |  | |
| Material Transfer agreement (MTA) | If applicable |  |  | |
| Validated questionnaire | Yes, if applicable |  |  | |
| Non-validated questionnaire | Yes, if applicable |  |  | |
| Interview topic guides | Yes, if applicable |  |  | |
| Letters/emails of invitation to participants | Yes, if applicable |  |  | |
| Letters and/or information sheets for GP/consultant | Yes, if applicable |  |  | |
| Manufacturers Authorisation | Essential *when IMP not hospital stock* |  |  | |
| The importer’s authorisation and Qualified Person declaration on [good manufacturing practice](https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice) for each manufacturing site | See guidance |  |  | |
| The European Medicines Agency’s (EMA) decision on the paediatric investigation plan and the opinion of the paediatric committee | See guidance |  |  | |
| Investigator’s Brochure (IB) | Yes, if applicable |  |  | |
| Summary of Product Characteristics (SmPC) | Yes, if applicable |  |  | |
| Investigational Medical Product Dossier (IMPD) or a simplified IMPD | See guidance |  |  | |
| Non-investigational medicinal product dossier | When *in use* Yes if applicable |  |  | |
| Investigational Medicinal Product (IMP) label template | Yes, if applicable |  |  | |
| A summary of scientific advice from any Member State or EMA if available | See guidance |  |  | |
| Sponsor Pharmacy approval | Essential |  |  | |
| Sponsor Medical/Clinical physics approval | See guidance |  |  | |
| Sponsor Radiology approval | See guidance |  |  | |
| Sponsor Pathology approval | See guidance |  |  | |
| Sponsor Gene therapy Committee approval | See guidance |  |  | |
| Sponsor Gene Modification (GM) approval |  |  |  | |
| Evidence of appropriate translation | See guidance |  |  | |
| Any other documents you think would be relevant to the submission | See guidance |  | | |
| Device section: |  |  | |  |
| List Equipment/Devices to be used  Name | For clinical use | Within Conformité Européene (CE) indication | | Is item loaned/ gifted?  If loaned of gifted is the item Master Indemnity Agreement (MIA) registered purchased |
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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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| All documents that will be submitted to the MHRA, HRA and HRA should be submitted.  All documents should be submitted in word format (editable format) and in draft. | |
| 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. |
| Research Protocol | On relevant JRMO template |
| PIS | For all studies that involve prospectively recruiting patients or healthy volunteers. Not applicable for some studies. HRA guidance available.  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) | For all studies that involve prospectively recruiting and consenting patients or healthy volunteers. Not applicable for some studies. HRA guidance available.  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. |
| Scientific peer review | 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 review to justify why not. |
| Departmental authorisation | Letter/email authorisation of appropriate person within the department in which the research will take place |
| Letter from statistician | This is to evidence statistician accountability and awareness for the statistical methods described in the protocol.  A standalone letter from the statistician is preferred but the MHRA has been known to accept a statistician’s signature on the protocol. NB If the statistician is external then a contract is required. |
| Researcher training certificate | GCP or Research Governance Framework for Health and Social Care (RGF) training. To book please see: <http://www.jrmo.org.uk/news-and-training/training/> |
| Costings | Please see following link to the online costing questionnaire: <https://webapps2.is.qmul.ac.uk/ecosting/> If there are no costs a No Cost Declaration Form is to be completed. |
| Curriculum Vitae | CI signed and dated. |
| HRA Statement of Activities | Needed for multi-site studies. 1 form for each site *type* |
| HRA Schedule of Events | Needed for multi-site studies. 1 form for each site *type* |
| Validated questionnaire | Evidence of the copyright |
| Manufacturers Authorisation | Required unless hospital stock to be used |
| The importer’s authorisation and Qualified Person declaration on [good manufacturing practice](https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice) for each manufacturing site | Required if IMP manufacturer outside EU |
| The EMA’s decision on the paediatric investigation plan and the opinion of the paediatric committee | A paediatric investigation plan (PIP) is a development plan aimed at ensuring that the necessary data are obtained through studies in children, to support the authorisation of a medicine for children. All applications for marketing authorisation for new medicines have to include the results of studies as described in an agreed PIP unless the medicine is exempt because of a deferral or waiver. This requirement also applies when a marketing-authorisation holder wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorised and covered by intellectual property rights. |
| IB | Required if IMP is unlicensed, specify version and date for each document submitted |
| SmPC | Required for licenced IMPs, specify version and date for each document submitted |
| IMPD or a simplified IMPD | A full IMPD is required when little or no information about an IMP has been previously submitted to competent authorities, when it is not possible to cross-refer to data submitted by another sponsor and/or when there is no marketing authorisation in the Community.  However, there are situations where a simplified IMPD will be sufficient. A simplified IMPD may be submitted if information has been assessed previously as part of a Marketing Authorisation in any member state or a clinical trial to that competent authority.  There are also situations where the SmPC of a Marketed Product will suffice as the IMPD. A SmPC may be submitted if the IMP has a Marketing Authorisation in any EU Member State and is being used in the same form, for the same indication and with a dosing regimen covered by the SmPC. The SmPC will also be sufficient for studies of dosing regimens where the sponsor can demonstrate that information in the SmPC justifies the safety of the new dosing regimen. |
| Non-IMP dossier | As a general rule, the documentation requirements in the application dossier for IMPs also apply to Non-IMPs. However, there are possibilities for simplified documentation requirements ('simplified dossier') depending on the extent of knowledge of the NIMP.  See for more information: https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-10/imp\_03-2011.pdf |
| IMP label template | This should be created in consultation with the sponsor pharmacy representative. |
| A summary of scientific advice from any Member State or the EMA if available | The EMA can give scientific advice and protocol assistance to medicine developers. For human medicines, scientific advice and protocol assistance are given by the Committee for Medicinal Products for Human Use (CHMP) on the recommendation of the Scientific Advice Working Party (SAWP).  Scientific advice is when the Agency gives advice to a developer on the appropriate tests and studies in the development of a medicine. This is designed to facilitate the development and availability of high-quality, effective and acceptably safe medicines, for the benefit of patients.  Medicine developers can request scientific advice from the EMA at any stage of development of a medicine, whether the medicine is eligible for the centralised authorisation procedure or not. |
| Sponsor Medical 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) |
| Sponsor Radiology approval | Needed when there is any imaging performed with in the protocol. Please contact: [salma.abdullahi3@nhs.net](mailto:salma.abdullahi3@nhs.net) and [claudio.melchiorri@nhs.net](mailto:claudio.melchiorri@nhs.net)  To initiate the local imaging review please forward the following: IRAS, Protocol, PIS, and Imaging Manual (if available) |
| Sponsor Pathology approval | Needed when Barts Health pathology will act as a central facility or a blood product is in use. Please contact: [aisha.hassan1@nhs.net](mailto:aisha.hassan1@nhs.net) and [claudio.melchiorri@nhs.net](mailto:claudio.melchiorri@nhs.net) |
| Sponsor Pharmacy approval | For local pharmacy involvement, pharmacy must be informed as early as possible via [rlhpharmacyct.bartshealth@nhs.net](mailto:rlhpharmacyct.bartshealth@nhs.net), [stuart.chandler@nhs.net](mailto:stuart.chandler@nhs.net) & and [claudio.melchiorri@nhs.net](mailto: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. |
| Sponsor Gene therapy Committee approval | Needed for all GM products. Please contact: Dr Mark Ariyanayagam [m.r.ariyanayagam@qmul.ac.uk](mailto:m.r.ariyanayagam@qmul.ac.uk) School of Medicine and Dentistry (SMD) Faculty H&S Manager / Biological Safety Adviser |
| 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. The translation service will be considered a vendor and must undergo JRMO contract and vendor assessment processes. |