**Procedure for requesting sponsorship:**

* Please read the SLaM/IoPPN R&D Office Sponsorship Guidance documents before completing this form.
* Please email this completed form and the study documents that apply in the table below to the SLaM/IoPPN R&D office - slam-ioppn.research@kcl.ac.uk

If you would like a research facilitator to go through any part of this form with you please contact the R&D office.

|  |
| --- |
| **Supporting documents - please attach copies of the following documents or indicate if they are not relevant for your study**  Full details of these are included in the sponsorship guidance |
| **Document** | **Attached?** **Yes/Not applicable** |
| **Yes**  | **N/A** |
| Sponsorship request form  |  |  |
| IRAS application form |  |  |
| CV for Chief Investigator |  |  |
| CV for Academic Supervisor and students (educational studies) |  |  |
| Protocol |  |  |
| PIS & Consent documents |  |  |
| Funding award letter  |  |  |
| Organisation Information Document (OID) formulti-site studies only |  |  |
| HRA Schedule of Events or SOECAT (if done at funding stage) |  |  |
| Confirmation of funding award from BRC (email or letter) for BRC funded studies |  |  |
| SLaM-IoPPN Costings form (for studies with no external funding) |  |  |
| Confirmation of scientific peer review - (either 2 x external reviews, confirmation of internal peer review from R&D office, or competitively awarded funding for single project) **OR** PAF for student projects |  |  |
| Confirmation completion of risk assessment (for studies involving administration of a drug/substance or otherwise deemed to be high-risk) |  |  |
| MHRA /KHP CTO confirmation of non-CTIMP (for studies involving a drug that are non-CTIMPs) |  |  |
| Confirmation of KCL insurance inclusion (if any of the exclusions apply) |  |  |
| HTA Denmark Hill Campus tissue form and email from Claire Troakes / Bernard Freeman (if using human tissue) |   |   |
| Email confirmation from Gursharan Kalsi if study involved the NIHR Bioresource  |  |  |

**SECTION A –PROJECT / CONTACT INFORMATION**

|  |
| --- |
| **Chief Investigator**   |
| Name |  |
| Department |  |
| Substantive employer (KCL or SLaM) |  |
| Please give details if substantively employed by another organisation |   |
| Details of honorary employment |  |
|  |  |
| **Key contact (if different to above)**   |
| Name |  |
| Contact details |  |
|  |  |
|  |  |

|  |
| --- |
| **Project information**  |
| Project Short Title |  |
| IRAS ID (located in project area on IRAS) |  |
| Outline any student involvement – even if the project is not primarily for educational purposes |  |
| **SECTION B – INSURANCE EXCLUSIONS** |  |
| **KCL insurance (KCL employees/students only)** (please refer to the KCL indemnity section of the Sponsorship Guidance) |
| Do any of the KCL indemnity exclusions outlined in the sponsorship guidance apply?(*If yes, please include confirmation of inclusion from Herman Codner*) |  Yes No  |
| **SECTION C – HUMAN TISSUE SAMPLES**  |  |
| **Does the study involve collection of human tissue? (If yes, refer to the Human Tissue Samples guidance document in the sponsorship guidance and complete the relevant sections below)** |  Yes No |
| Will any tissue samples be transferred between sites? If yes, please give details of what will be transferred and to which organisations (please include the BioResource and labs) |  Yes No  |
| Will any tissue samples be stored at the IoPPN? If yes, please attach the HTA Denmark Hill Campus tissue form (in the sponsorship guidance) and email from Claire Troakes / Bernard Freeman |  Yes No |
| Will the NIHR Bioresource be involved with collection, transfer, storage or analysis of your study samples? If yes, please attach the email confirmation from Gursharan Kalsi at the Bioresource | Yes No |

**SECTION D – IMP**

|  |  |
| --- | --- |
| **Does the study involve the administration of a drug or other substance?**   | Yes No |
| If yes, is the study a CTIMP (Clinical Trial of an Investigational Medicinal Product) Yes No*If no, please attach confirmation of non-CTIMP from MHRA or the KHP-CTO**For all studies involving a drug, please attach confirmation of approval by IoPPN/SLaM risk assessment committee. Please contact the R&D office if a risk assessment approval has not yet been obtained*  |

|  |  |
| --- | --- |
| **SECTION E - FUNDING** |  |
| **Is there funding in place to cover all of the activities in the protocol/IRAS form?**Please complete the following funding sections that apply to your study |  Yes No |
|  |  |
| **Please complete this section for externally funded studies (including studentships) complete one entry per funding award and attach the funding award letters** |
| Funding organisation 1 |   |
| Grant Title |   |
| Amount awarded |   |
| Organisation receiving the funding (KCL or SLaM) |   |
| Funders Ref |   |
| IoPPN Research Grants Cost code (if applicable) |   |
| Will any funding be provided for/ transferred to other sites (if yes please give details below)  Yes No  |
|  |
| If yes, is this covered by a sub-contract or collaboration agreement (give details) Yes No  |
|  |
| Has the funder stipulated a mandatory start date?  |   |
|  |
| Funding organisation 2 |   |
| Grant Title |   |
| Amount awarded |   |
| Organisation receiving the funding (KCL or SLaM) |   |
| Funders Ref |   |
| IoPPN Research Grants Cost code (if applicable) |   |
| Will any funding be provided for/ transferred to other sites (if yes please give details below)  Yes No  |
|  |
| If yes, is this covered by a sub-contract or collaboration agreement (give details) Yes No  |
|  |
| Has the funder stipulated a mandatory start date?  |   |

|  |
| --- |
| **Complete this section for BRC funded studies and attach confirmation of the funding** |
| Details of BRC funding |   |
| Amount awarded |   |
| What does this cover? |   |
|  |  |
| **Complete these sections if the costs of the study are not entirely covered by external or BRC funding.** Please give details of how the study costs will be covered (please attach the SLaM R&D costings form and email confirmation from the Dept/CAG that they will cover the cost of the study)  |
|  |
| Please include below an explanation as to why you are proposing to conduct the study without awarded funding (for example, feasibility study in order to seek external grant funding)  |
|  |

|  |
| --- |
|  |
| **Excess Treatment Costs – SOECAT*****If you have not completed a SoECAT form at the funding application stage, you may need to complete a SOECAT form now as part of your HRA application, if your study meets the following criteria:*** |
| Your study is eligible for the NIHR Portfolio <https://www.nihr.ac.uk/funding-and-support/study-support-service/eligibility-for-nihr-support/>  |
| Your study is categorised as interventional (i.e. clinical trial - one of the first 4 project categories on IRAS) |
| Your study is non-interventional, but may impact treatment for NHS patients |
| The SoECAT form and guidance is in the sponsorship guidance pack – contact the R&D office if you have any questions about the form. The R&D office will advise you whether a SoECAT is needed.  |

**SECTION F – SERVICE PROVISIONS**

|  |
| --- |
| We will need details of any organisations, services or committees that will be involved in the management of, or provide services for this project, e.g. labs, pharmacies, couriers (including CitySprint) clinical trials units, trial steering committee, DMEC, transcription services, translators, software companies, emergency code break service. Include imaging centres such as CNS and Invicro (formerly Imanova) Please give details including what has been discussed / agreed / finalisedIf there any agreements in place with the organisations, services or committees please include copies with the sponsorship documents or describe the state of completion.This information will help us to identify any contracts and agreements needed at the outset |

Please indicate which (if any) of the following organisations, services or committees will be involved in the management of, or provide services for this project

|  |  |
| --- | --- |
| Labs | Yes / No |
| Details: |  |

|  |  |
| --- | --- |
| Pharmacy | Yes / No |
| Details: |  |

|  |  |
| --- | --- |
| Couriers (i.e. CitySprint) | Yes /No |
| Details: |  |

|  |  |
| --- | --- |
| Clinical Trials Unit  | Yes / No |
| If yes, which CTU are you using and what services are they providing: |  |
| * Randomisation
* Database
* Statistical input
 |  |

|  |  |
| --- | --- |
| Emergency code break service | Yes / No |
| Details: |  |

|  |  |
| --- | --- |
| Will you use any software companies / websites / electronic devices/ smartphone/tablet apps  | Yes / No |
| Details: |  |
| New methods of data processing – have you checked with KCL Information Compliance whether a [DPIA](https://internal.kcl.ac.uk/about/secretariat/business-assurance/compliance/gdpr/Data-Protection-Impact-Assessments) is needed?  |  |
| ! Please submit associated contracts/agreements with your application! |  |

|  |  |
| --- | --- |
| Translators or Transcription services | Yes /No |
| Details: |  |

|  |  |
| --- | --- |
| Will you be setting up the following: |  |
| Trial Steering Committee (TSC)Data Monitoring Committee (DMEC) |  |

|  |  |
| --- | --- |
| **Will you use any of the following facilities:** |  |
| Centre for Neuroimaging Sciences (CNS) |  |
| Invicro (Imanova) |  |
| Denmark Hill CRF |  |
| Other imaging or CRF facility; please state |  |

**SECTION G – RESEARCH SITES**

|  |
| --- |
| **Sites - please ensure that all confirmed sites are listed in Part C of the IRAS form** |
| Is there an intention to add new sites in future? |   |
| Would the study be open to new sites? |   |