

**Research Office Sponsorship Guidance**

***If you wish to conduct research at KCH we will need to review your application before it is submitted to Regulatory Bodies; if we are sponsoring or co-sponsoring your study, it will need to be reviewed before it can be signed off.***

The UK Policy Framework for Health and Social Care Research (2017) requires all studies to have an identified ‘Sponsor’. The Sponsor is an institution or organisation which takes on the legal responsibility for the initiation and management of the research. A sponsor’s responsibilities include ensuring that:

* the resources are adequate to allow the collection, analysis, & protection of high quality research data;
* the project is scientifically sound; and
* Indemnities are in place to cover those who are conducting or participating in research.

The institution will delegate the responsibility for issuing sponsorship to an individual who will sign the IRAS form on their behalf.

You will need to identify an institution that is willing to take on this role. The sponsor will generally be the organisation employing the Chief Investigator.

* KCH will generally sponsor studies when a Trust employee is acting as the Chief Investigator (CI).
* If the CI is a KCL employee and the research will take place in the NHS, then the College will act as sponsor and KCH review the application to determine if co-sponsorship is required.

Please note that on-going Sponsorship & Trust Management approval are subject to compliance with the conditions of Confirmation of capacity and capability.

## Obtaining sponsorship

The Research & Innovation Office at KCH will review your IRAS application to ensure that it complies with national regulations and will advise when you are ready to apply for sponsorship. Please contact the Research Office as soon as possible to organise review.

The IRAS form must be submitted to the Sponsor for electronic signature **before** booking a date with Ethics/HRA. You will need to complete the KCH feasibility process before sponsorship can be obtained. More details of this and further guidance and help are available from the Research & Innovation Office.

## CTIMPs

Where KCH is to sponsor a Clinical Trial of Investigational Medicinal Product (CTIMP) some of the sponsor’s responsibilities are undertaken by the King’s Health Partners Clinical Trials Office (KHP CTO).

For co-sponsored CTIMPs where the CI is a KCL employee, applicants will need to obtain College level signature, which will be coordinated through the KHP CTO quality team as part of preparing the application. Your CRA will advise you of the details to enter in the form, and how to obtain signature. Further details will be found on the KHP CTO website: <http://www.khpcto.co.uk/>

## Student research

In general, the educational institution will act as Sponsor; the pre-submission review conducted at KCH will determine if alternative arrangements are required.

The table, below, contains the required sponsor information for inclusion within your IRAS application.

# All studies other than Clinical Trials of Investigational Medicinal Products (CTIMPs)

|  |  |  |  |
| --- | --- | --- | --- |
| **KCH sponsored** | **KCL - KCH co-sponsored** | **KCL sole sponsored** | **KCH acting as National Coordinating Centre** |
| **A4: Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?** | | | |
| The R&D Office | First Floor Coldharbour Works | 245A Coldharbour Lane | Brixton | London SW9 8RR  Tel: 020 3299 1980  Email: [kch-tr.research@nhs.net](mailto:kch-tr.research@nhs.net) | Professor Bashir Al-Hashimi  Vice President (Research and Innovation)  King’s College London  Room 8.11, 8th Floor Melbourne House  44-46 Aldwych  London WC2B 4LL  Tel: 02078487306  Email [vpri@kcl.ac.uk](mailto:vpri@kcl.ac.uk) | Professor Bashir Al-Hashimi  Vice President (Research and Innovation)  King’s College London  Room 8.11, 8th Floor Melbourne House  44-46 Aldwych  London WC2B 4LL  Tel: 02078487306  Email [vpri@kcl.ac.uk](mailto:vpri@kcl.ac.uk) | The R&D Office | First Floor Coldharbour Works | 245A Coldharbour Lane | Brixton | London SW9 8RR  Tel: 020 3299 1980  Email: [kch-tr.research@nhs.net](mailto:kch-tr.research@nhs.net) |
| **A64-1**: **Sponsor** | | | |
| Jasmine Palmer  Research & Development Governance Manager  King’s College Hospital NHS Foundation Trust  The R&D Office | First Floor Coldharbour Works | 245A Coldharbour Lane | Brixton | London SW9 8RR  Tel: 020 3299 1980  Email: [kch-tr.research@nhs.net](mailto:kch-tr.research@nhs.net) | Professor Bashir Al-Hashimi, as above.  **Co-Sponsor**:  Jasmine Palmer  Research & Development Governance Manager  King’s College Hospital NHS Foundation Trust  The R&D Office | First Floor Coldharbour Works | 245A Coldharbour Lane | Brixton | London SW9 8RR  Tel: 020 3299 1980  Email: [kch-tr.research@nhs.net](mailto:kch-tr.research@nhs.net) | Professor Bashir Al-Hashimi  Vice President (Research and Innovation)  King’s College London  Room 8.11, 8th Floor Melbourne House  44-46 Aldwych  London WC2B 4LL  Tel: 02078487306  Email [vpri@kcl.ac.uk](mailto:vpri@kcl.ac.uk) | Overseas Sponsor Representative details |
| **A64−2: Please explain how the responsibilities of sponsorship will be assigned between the co-sponsors** | | | |
| N/A | "The lead sponsor, King's College  London, will take primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. King's College London also provides cover under it's No Fault Compensation Insurance, which provides for payment of damages or compensation in respect of any claim made by a research subject for bodily injury arising out of participation in a clinical trial or healthy volunteer study (with certain restrictions). The co-sponsor, King's College Hospital, takes ultimate responsibility for arranging the initiation and management of this research, and will take responsibility for ensuring that appropriate standards, conduct and reporting are adhered to regarding its facilities and staff involved with the project. King’s College Hospital will also undertake the governance review for the project and provide cover for clinical negligence by any of its staff in undertaking the research, under the CNST scheme managed by the NHS  LA" | N/A | N/A |
|  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **A68: Give details of the lead NHS R&D contact for this research** | | | |
| King’s College Hospital NHS Foundation Trust  The R&D Office | First Floor Coldharbour Works | 245A Coldharbour Lane | Brixton | London SW9 8RR  Tel: 020 3299 1980  E-mail: [kch-tr.research@nhs.net](mailto:kch-tr.research@nhs.net) | King’s College Hospital NHS Foundation Trust  The R&D Office | First Floor Coldharbour Works | 245A Coldharbour Lane | Brixton | London SW9 8RR  Tel: 020 3299 1980  E-mail: [kch-tr.research@nhs.net](mailto:kch-tr.research@nhs.net) | King’s College Hospital NHS Foundation Trust  The R&D Office | First Floor Coldharbour Works | 245A Coldharbour Lane | Brixton | London SW9 8RR  Tel: 020 3299 1980  E-mail: [kch-tr.research@nhs.net](mailto:kch-tr.research@nhs.net) | King’s College Hospital NHS Foundation Trust  The R&D Office | First Floor Coldharbour Works | 245A Coldharbour Lane | Brixton | London SW9 8RR  Tel: 020 3299 1980  E-mail: [kch-tr.research@nhs.net](mailto:kch-tr.research@nhs.net) |

|  |  |  |  |
| --- | --- | --- | --- |
| **A74. What arrangements are in place for monitoring and auditing the conduct of the research?** | | | |
| "The monitoring and auditing of the conduct of research within the Trust lies with the R&D office. The Chief Investigator will take responsibility for the day to day management of the study. The R & I Office on behalf of the Sponsor may monitor and conduct random audits on a selection of studies in its clinical research portfolio, or may conduct for-cause monitoring visits following an incident  or a breach or GCP or Protocol" | "KCL will take responsibility for ensuring adherence to GCP e.g. implementation, maintenance and monitoring of GCP and GCP-related procedures" | "KCL will take responsibility for ensuring adherence to GCP e.g. implementation, maintenance and monitoring of GCP and | Other insurance – Overseas sponsor indemnity details |
| **A76−1: What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising**  **from the management of the research?** | | | |
| NHS indemnity applies | Other insurance- KCL insurance applies | Other insurance- KCL insurance applies | Other insurance – Overseas sponsor insurance details |
| **A76-2: What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to**  **participants arising from the design of the research?** | | | |
| NHS indemnity applies | Other insurance- KCL indemnity applies | Other insurance- KCL insurance applies | Other insurance – Overseas sponsor indemnity details |
| **A76-3: What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm**  **to participants in the conduct of the research?** | | | |
| NHS indemnity applies | NHS indemnity applies | Other insurance- KCL insurance applies | Other insurance – Overseas sponsor indemnity details |

* 1. **All Clinical Trials of Investigational Medicinal Products (CTIMPs)**

|  |  |  |
| --- | --- | --- |
| **KCH sole sponsored CTIMPs** | **KCL - KCH co-sponsored CTIMPs** | **KCL sole sponsored CTIMPs** |
| **A4: Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?** | | |
| Amy Holton Quality Manager  Kings Health Partners Clinical Trials Office 16th Floor, Tower Wing,  Guys Hospital, Great Maze Pond, London,  SE1 9RT  Tel: 020 7188 5732  E-mail: amy.holton@kcl.ac.uk | Amy Holton Quality Manager  Kings Health Partners Clinical Trials Office 16th Floor, Tower Wing,  Guys Hospital, Great Maze Pond, London,  SE1 9RT  Tel: 020 7188 5732  E-mail: amy.holton@kcl.ac.uk | Amy Holton Quality Manager  Kings Health Partners Clinical Trials Office 16th Floor, Tower Wing,  Guys Hospital, Great Maze Pond, London,  SE1 9RT  Tel: 020 7188 5732  E-mail: amy.holton@kcl.ac.uk |
| **A64-1**: **Sponsor** | | |
| Jasmine Palmer  Research & Development Governance Manager  King’s College Hospital NHS Foundation Trust  The R&D Office | First Floor Coldharbour Works | 245A Coldharbour Lane | Brixton | London SW9 8RR  e-mail: [kch-tr.research@nhs.net](mailto:kch-tr.research@nhs.net) | Professor Richard Trembath  Provost/Senior Vice President (Health)  Guy’s Campus  King’s College London SE1 9RT  Tel: tel:+44 (0) 20 7848 6391  E-mail: richard.trembath@kcl.ac.uk  **Co-Sponsor**: Jasmine Palmer  Research & Development Governance Manager King’s College Hospital NHS Foundation Trust  The R&D Office | First Floor Coldharbour Works | 245A Coldharbour Lane | Brixton | London SW9 8RR  Tel: 020 3299 6625  e-mail: [kch-tr.research@nhs.net](mailto:kch-tr.research@nhs.net) | Professor Richard Trembath  Provost/Senior Vice President (Health)  Guy’s Campus  King’s College London SE1 9RT  Tel: tel:+44 (0) 20 7848 6391  E-mail: richard.trembath@kcl.ac.uk |

|  |  |  |
| --- | --- | --- |
| **A64−2: Please explain how the responsibilities of sponsorship will be assigned between the co-sponsors** | | |
| N/A | "The lead sponsor, King's College London, will take primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. King's College London also provides cover under it's No Fault Compensation Insurance, which provides for payment of damages or compensation in respect of any claim made by a research subject for bodily injury arising out of participation in a clinical trial or healthy volunteer study (with certain restrictions). The co-sponsor, King's College Hospital, takes ultimate responsibility for arranging the initiation and management of this research, and will take responsibility for ensuring that appropriate standards, conduct and reporting are adhered to regarding its facilities and staff  involved with the project. King’s College Hospital will also undertake the governance review for the project and provide cover for clinical negligence by any of its staff in undertaking the research, under  the CNST scheme managed by the NHS LA" | N/A |
| **A68: Give details of the lead NHS R&D contact for this research** | | |
| The R&D Office,  King’s College Hospital NHS Foundation Trust  The R&D Office | First Floor Coldharbour Works | 245A Coldharbour Lane | Brixton | London SW9 8RR  Tel: 020 3299 1980  E-mail: [kch-tr.research@nhs.net](mailto:kch-tr.research@nhs.net) | The R&D Office,  King’s College Hospital NHS Foundation Trust  The R&D Office | First Floor Coldharbour Works | 245A Coldharbour Lane | Brixton | London SW9 8RR  Tel: 020 3299 1980  E-mail: [kch-tr.research@nhs.net](mailto:kch-tr.research@nhs.net) | The R&D Office,  King’s College Hospital NHS Foundation Trust  The R&D Office | First Floor Coldharbour Works | 245A Coldharbour Lane | Brixton | London SW9 8RR  E-mail: [kch-tr.research@nhs.net](mailto:kch-tr.research@nhs.net) |
| **A74. What arrangements are in place for monitoring and auditing the conduct of the research?** | | |
| The KHP CTO will take responsibility for monitoring and auditing the conduct of research for CTIMPs. Each study will be assigned a CRA who will conduct  monitoring visits; the frequency and type of visits to | The KHP CTO will take responsibility for monitoring and auditing the conduct of research for CTIMPs. Each study will be assigned a CRA who will conduct  monitoring visits; the frequency and type of visits to | The KHP CTO will take responsibility for monitoring and auditing the conduct of research for CTIMPs. Each study will be assigned a CRA who will conduct  monitoring visits; the frequency and type of visits to |

|  |  |  |
| --- | --- | --- |
| be based on the outcome of the risk assessment" | be based on the outcome of the risk assessment" | be based on the outcome of the risk assessment" |
| **A76−1: What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising**  **from the management of the research** | | |
| NHS indemnity applies | Other insurance- KCL insurance applies | Other insurance- KCL insurance applies |
| **A76-2: What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to**  **participants arising from the design of the research?** | | |
| NHS indemnity applies | Other insurance- KCL insurance applies | Other insurance- KCL insurance applies |
| **A76-3: What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm**  **to participants in the conduct of the research?** | | |
| NHS indemnity applies | NHS indemnity applies | Other insurance- KCL insurance applies |