

Research Office

Sponsorship Guidance

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

The Research Governance Framework (2005) 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.

| KCH sponsored | KCL - KCH co-sponsored | KCL-KCH co-sponsored (CTIMPs) | KCL sole sponsored |
|--|--|---|--|
| A4: Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project? | | | |
| <p>The R&D Office, King's College Hospital NHS Foundation Trust 161 Denmark Hill, LONDON, SE5 8EF. Tel: 020 3299 1980 Fax: 020 3299 5155 e-mail: kch-tr.research@nhs.net</p> | <p>Keith Brennan, Director of Research Management & Director of Administration (Health Schools), Room 1.8 Hodgkin Building, Guy's Campus, King's College London, LONDON, SE1 4UL. Tel: 020 7848 6960 E-mail: keith.brennan@kcl.ac.uk</p> | <p>Helen Critchley 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: helen.critchley@kcl.ac.uk</p> | <p>Keith Brennan, Director of Research Management & Director of Administration (Health Schools), Room 1.8 Hodgkin Building, Guy's Campus, King's College London, LONDON, SE1 4UL. Tel: 020 7848 6960 E-mail: keith.brennan@kcl.ac.uk</p> |
| A64-1: Sponsor (or Legal Representative) | | | |
| <p>Liba Stones R&D Manager King's College Hospital NHS Foundation Trust 161 Denmark Hill, LONDON, SE5 8EF. Tel: 020 3299 3841 Fax: 020 3299 5155 e-mail: kch-tr.research@nhs.net</p> | <p>Keith Brennan, as above.</p> <p>Co-Sponsor: Liba Stones R&D Manager King's College Hospital NHS Foundation Trust 161 Denmark Hill, LONDON, SE5 8EF. Tel: 020 3299 3841 Fax: 020 3299 5155 e-mail: kch-tr.research@nhs.net</p> | <p>Professor Robert Lechler Vice Principal (Health) Counting House Guy's Campus King's College London SE1 4UL Tel: 0207 188 8794 E-mail: Robert.lechler@kcl.ac.uk</p> <p>Co-Sponsor: Liba Stones R&D Manager King's College Hospital NHS Foundation Trust 161 Denmark Hill, LONDON, SE5 8EF. Tel: 020 3299 3841 Fax: 020 3299 5155 e-mail: kch-tr.research@nhs.net</p> | <p>Keith Brennan, Director of Research Management & Director of Administration (Health Schools), Room 1.8 Hodgkin Building, Guy's Campus, King's College London, LONDON, SE1 4UL. Tel: 020 7848 6960 E-mail: keith.brennan@kcl.ac.uk</p> |
| A64-2: Please explain how the responsibilities of sponsorship will be assigned between the co-sponsors | | | |

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| N/A | <p>"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"</p> | <p>"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"</p> | N/A |
| A68: Give details of the lead NHS R&D contact for this research | | | |
| <p>The R&D Office, King's College Hospital NHS Foundation Trust 161 Denmark Hill, LONDON, SE5 8EF. Tel: 020 3299 1980</p> | <p>The R&D Office, King's College Hospital NHS Foundation Trust 161 Denmark Hill, LONDON, SE5 8EF. Tel: 020 3299 1980 Fax: 020 3299 5155</p> | <p>The R&D Office, King's College Hospital NHS Foundation Trust 161 Denmark Hill, LONDON, SE5 8EF. Tel: 020 3299 1980</p> | <p>Research Facilitator to advise</p> |

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| Fax: 020 3299 5155 e-mail: kch-tr.research@nhs.net | e-mail: kch-tr.research@nhs.net | Fax: 020 3299 5155 E-mail: 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&I 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 of GCP or Protocol" | "KCL will take responsibility for ensuring adherence to GCP e.g. implementation, maintenance and monitoring of GCP and GCP-related procedures" | 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" | "KCL will take responsibility for ensuring adherence to GCP e.g. implementation, maintenance and monitoring of GCP and |
| 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 indemnity applies | Other insurance- KCL indemnity applies | Other insurance- KCL indemnity 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 indemnity applies | Other insurance- KCL indemnity applies | Other insurance- KCL indemnity 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 | NHS indemnity applies | Research Facilitator to advise |