APPLYING FOR RESEARCH FUNDING – PREPARING A PROPOSAL

This document contains information on preparing and submitting proposals, including internal approval steps to follow. It does not cover costing and pricing information, which is contained in the Costing & Pricing pdf. The document has been put together by the Research Grants and Contracts office (RG&C). References to the Pre-award Team applies to the main Pre-award Team and/or the EU Pre-award Team (as applicable to the funder).

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Weeks before intended date of submission of proposal to funder:

4-6+ weeks	Make first contact with key KCL and external parties, including Pre-award staff
2-3+ weeks	Finish application form and complete KCL RG Form
1+ weeks	Pre-award checks, proposal revision / correction, authorisation and submission

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A. KING'S REQUIREMENTS

1. Check your project can be handled as research

The King's processes mentioned here apply to research work only, non-research work has different requirements (e.g. government reporting requirements, VAT implications etc.) so it's important to classify the work correctly.

For a project to be classifiable as research, it must meet 3 definitions and requirements: Charity Commission requirements, Frascati and REF definitions of research. The definitions focus on *the creation of new knowledge,* whereas CC's requirements focus on the creation and dissemination of the work for the public benefit. For further information see Section D.

2. Check your eligibility to hold a grant

Please see Section E for details of King's regulations on who can hold a grant.

Please check the eligibility rules of the specific funding scheme, many schemes are quite explicit about the people who should apply (e.g. the applicable experience / stage of career) etc. Eligibility is commonly quoted by funders as the reason for applications being rejected.

3. Quote authorised costs in your proposal

The Costing and Pricing document has information on budgeting projects.

For King's staff (existing as well as future new posts) costs and staff-related costs (i.e. overheads, which under Full Economic Costs are known as Indirect Costs and Estates Costs), these have to be provided by the Pre-Award team. Submit a Staff Cost Request Form to obtain these costs for a proposal. Include all staff working on the project, regardless of whether funding will be provided for such staff, as HEFCE requires King's to record the total cost of its projects for monitoring purposes.

4. Obtain King's approvals to submit a proposal

All applications, official quotations and tenders, where any funding will come to King's, must be signed off by the Pre-Award team before submission. This includes proposals being led by other institutions. Pre-Award sign-off as *Administrative Authority*, *Institutional Official, Finance Officer* or equivalent.

For Pre-Award to approve, they

- Check the funder's terms and conditions are acceptable
- Check the proposal has been completed correctly, in accordance with the funder's requirements and King's policies
- Must receive an RG form, approved by School authorised signatories

Unless alternative internal deadlines have been specified, to obtain approval, send the information required to Pre-Award 5 working days before you intend your proposal to be sent to the funder. Proposals are reviewed on a first come, first served basis.

Why 5 days? The Pre-Award team is quite small and they are handling new funder deadlines every week, high volumes of applications (approx 2000 per year), hundreds of requests for costs, lots of awards (approx. 1000 per year) and negotiating associated legal contracts. 5 days allows the Pre-Award team time to check a high volume of proposals and for applicants to make the requisite corrections to their proposal prior to submission.

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B. TIMESCALE FOR COMPLETING A PROPOSAL

Weeks before the intended date of submission of the proposal to the funding body:

1. 4-6+ weeks – Make preliminary contact with key internal & external parties

During this stage: Identify the funding opportunity, design the project, identify the resources needed and start to gather information on costs and availability of those resources.

Contact the Pre-Award team to obtain preliminary staff and staff-related costs

Staff costs and staff-related costs (i.e. indirect costs and estates costs) often form the major component of a project budget and, as such, it's important to ascertain these costs early in the development of a project proposal. These costs may lead to changes to the project scope, reconsideration of staffing requirements and/or funding scheme to which the project should be submitted.

Contact external parties to obtain their costs

NHS Trusts and universities can take a considerable amount of time to produce costs for a proposal, so it's advisable to contact these parties early on. Contact NHS Trusts if the project involves NHS Trust staff, facilities, patients and/or NHS patient data.

To obtain costs from KHP NHS Trusts, you will need to send them a detailed description of the proposed project.

Guy's & St Thomas' NHS Trust require 6 weeks notice to process an application, which includes providing costs and obtaining approvals from senior Trust staff.

King's College Hospital NHS Trust require at least 4 weeks notice.

SLAM / IOP office should be contacted as soon as possible.

2. 2-3 weeks – Finish proposal & complete College RG Form

During this stage: Finalise the project scope and resources, arrange peer review of the proposal (if not already done) and address areas of weakness identified through peer review.

For staff costs, if the requirements have changed since obtaining the preliminary costs, contact to the RG&C Pre-Award Team to provide a final set of figures.

Complete the application form and RG form. The RG form requires sign-off from the applicant(s) and School authorised signatories. Send the completed proposal and RG form to Pre-Award to check through.

If there is a 2-stage funder online approval process (e.g. Research Council applications via the je-s system), arrange approval by the first-stage approvers (typically designated School-level approvers).

3. 1+ weeks – Pre-Award checking, proposal revision / correction, authorisation & submission

The Pre-award team check each application and RG form, particularly the finance sections but also for completion in accordance with funder rules and compliance with King's policies.

The team find errors/issues with most proposals, that require revision before they can be authorised. Common errors for Research Council applications include:

1. Not all costs included in the budget are justified in the *Justification of Resources*
2. Missing attachments, ineligible attachments and attachments exceeding page/font limits
3. Figures have not been entered correctly (with some funder IT systems, Pre-Award staff can edit figures online, in consultation with applicants)

Applicants must be contactable during the checking process so that errors/issues can be resolved. In some cases, it's necessary to return proposals to applicants to correct via the funder's online submission system.

Pre-Award authorisation is via signature of paper application forms or completion of an online approval step. Online approval is frequently the *submitting step* for an application e.g. applications submitted via Je-s.

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C. WHAT CONSTITUTES RESEARCH?

King's has to be able to be free to publish the results of all externally-funded research projects that it carries out in accordance with normal academic practice, and to use those research results itself for further academic activity. Without these rights, research could not grow incrementally, income for projects could not be recorded in the College's finance ledgers as research income and may not be able to be included in the REF. These requirements are specific to research projects and do not apply to consultancy or service contracts. This in turn poses the question of what constitutes research.

The categorisation of research is not always straightforward because there are a number of grey areas, but it generally can be said to entail the creation of new knowledge and does not include the application of existing knowledge or expertise to solve specific problems where there is nothing novel being created.

There are three main definitions and requirements for research which King's uses, and it should be noted they are not wholly congruent. The REF and Frascati definitions are useful to help characterise the nature of work itself and supplement the requirements of the Charity Commission. However, all research must comply fully with the Commission's requirements and it is quite possible that a piece of work could fall within the REF definition of research but not comply with the Commission's requirements; such work cannot be accepted by King's as 'research' and counted as research income even though it would be able to be counted into the REF.

The Charity Commissioners' requirements

For research universities these requirements are detailed and complex and bring with them regulatory requirements and are external audited by HEFCE on behalf of the Commission. In brief, they require that for any activity to be classifiable as research it must:

- fit within the scope of the charitable mission of King's, as set out in its charter
- be capable of increasing or enhancing knowledge, understanding and learning
- be undertaken 'for the public benefit' and with the intention that the useful knowledge it generates will be disseminated to the public and others who are able to utilise or benefit from it. Dissemination has to take place within a 'reasonable time frame' after the research is completed or after the outcomes of value occur, and
- in the case of work involving commercial bodies, any benefit to a commercial collaborator is deemed to be non-charitable and so must be 'legitimately incidental' to the charitable 'public benefit' aims of King's and not outweigh public benefit. King's is also required to exercise an appropriate degree of control over the use of intellectual property rights and receive a proper share in benefits arising from their use.

REF definition of research

This definition is the fairly simple one used for the REF, which states that Research is "a process of investigation leading to new insights, effectively shared. It includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship*; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction.

It excludes routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research.

* Scholarship for the REF is defined as the creation, development and maintenance of the intellectual infrastructure of subjects and disciplines, in forms such as dictionaries, scholarly editions, catalogues and contributions to major research databases.

Frascati definition of research

The third definition is the so-called 'Frascati' definition which is taken from Chapter 2 of the OECD's 1993 'Frascati' Manual entitled 'Main Definitions And Conventions For The Measurement Of Research And Experimental Development'. HEFCE and HESA require the College to adopt this definition, and it is also used by UK Government departments to differentiate between 'research' and 'consultancy'. The Frascati manual defines research and breaks it down into three main categories of research:-

"Research and experimental development (R&D) comprise creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications. R&D is a term covering three activities: basic research, applied research, and experimental development.

Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view. Basic research analyses properties, structures, and relationships with a view to formulating and testing hypotheses, theories or laws. The results of basic research are not generally sold but are usually published in scientific journals or circulated to interested colleagues. Occasionally, basic research may be "classified" for security reasons.

Applied research is also original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective. The results of Applied Research are intended primarily to be valid for a single or limited number of products, operations, methods, or systems. Applied research develops ideas into operational form. The knowledge or information derived from it is often patented.

Experimental development is systematic work, drawing on existing knowledge gained from research and/or practical experience, that is directed to producing new materials, products or devices, to installing new processes, system and services, or to improving substantially those already produced or installed."

Research does not include running courses for outside organisations, the production of teaching materials that do not also embody original research, the provision of services (e.g. scanning) or consultancy*

In any areas of doubt or dispute Research Grants & Contracts will seek the advice and guidance of the Head of School in which any proposed work is intended to take place.

*** Consultancy**

Consultancy can be said to involve the deployment of existing knowledge for the resolution of specific problems presented by a client. It entails giving expert advice or problem-solving and applies a consultant's expert knowledge but does not involve the creation of new knowledge. Examples are:-

- Expert witness work
- Routine analysis, testing and validations services
- Environmental impact assessment, base-line studies etc.
- Hazards or Health & Safety assessment
- General purpose or routine data collection
- Reviews of procedures
- Professional Practice work (eg law, accounting, architecture, nursing, social work etc.)
- Supply of expert opinion
- Routine literature surveys
- Advising on protocols for clinical trials
- Sitting on external committees, enquiries etc.
- General purpose / routine data collection
- Feasibility studies
- Specialised routine medical care
- Routine computer programming, systems work or software maintenance (excluding research or development of software, programming languages or operating systems)
- Private or clinical private practice
- Policy reviews

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D. STAFF & ELIGIBILITY

1. King's rules on eligibility

The rules on who can hold a grant at King's are contained in the King's Financial Procedures. However, where the funder lays down particular eligibility criteria for a specific funding scheme, and where King's is willing to accept these criteria, they will take precedence over, or supplement, existing King's policies for that particular scheme and / or application only.

One of the key factors on which eligibility rules are based is the ability for King's to hold a person accountable for the successful completion and management of an award in accordance with the terms and conditions of the funder and compliance with College policies.

'**Successful completion**' in this Section refers to meeting all the funder's requirements for an award, which includes:

i. a requirement to undertake the research project in accordance with the terms and conditions of the award (including financial and scientific management); and

ii. a requirement to meet the reporting requirements, which may include a requirement to submit, and have accepted, a final scientific report and financial report by specified dates (for Research Councils this is 3 months after the grant end date), and

iii. a requirement to meet publication / dissemination requirements (e.g. Wellcome Trust final payment can be conditional on an academic publication being made within a period from the end date of the grant).

'Full project period' in this Section refers to the funded project duration plus the period thereafter required for completing the funder's requirements in terms of final reporting and publication / dissemmination tasks.

If a person is not employed by King's for the full project period, it is very difficult for King's to hold that person accountable for successful completion of the project. Allowing such people to have responsibility for grants / contracts awarded to King's exposes the institution to risks and, consequently, there are limited circumstances when this is permissible.

a) Staff on open-ended employment contracts

If an employment contract is planned to continue for the full project period, enabling a person to successfully complete their project, such staff may act as the King's lead Investigator on awards. This is true whether they are the sole King's investigator or there are other King's investigators involved.

b) Staff on fixed term employment contracts

If the fixed term employment contract is planned to exceed the full project period, enabling a person to successfully complete their project, such staff may act as the King's lead investigator on awards. This is true whether they are the sole King's investigator or there are other King's investigator's involved.

If the fixed term employment contract is not planned to exceed the full project period, then the following are possible options:

(a) The person is named as the King's lead investigator. This requires the staff member to at least be employed to the end of the grant (even if this is dependent on grant-funding). In addition, their School and Division/Department would have to make a written undertaking that (i) they intend to employ the staff member beyond the end of the award by sufficient time as to enable successful completion of the project, and (ii) if they are not able to fund the person beyond the end date, they provide the name of an alternative person who will be responsible and held accountable to King's for successful completion of the project.

(b) The person is named as the King's co-lead investigator or co-investigator. This requires a permanent King's employee to be involved in the award. The permanent employee would have to accept responsibility for the project and be held accountable for the successful completion of the project. In addition, the permanent employee would be the APTOS budget holder, i.e. the one to authorise project-related expenditure at King's.

c) Staff intending to retire during a proposed grant

Where a lead investigator anticipates that they may retire during the lifetime of an award that they are applying for, they should make this clear on their RG form and identify an alternative permanent member of King's staff on their RG form, who will take over lead-investigator responsibility on their retirement.

d) Emeritus staff and research assistants

Emeritus staff and research assistants are permitted to act as named co-lead investigators or co-investigators on awards where they have a permanent member of King's staff acting as a co-lead investigator on the project, who will be in the position to take responsibility to the funder on behalf of King's for successful completion of the project.

In certain circumstances, emeritus staff may be permitted to hold grants (but not contracts) in their own names as sole investigators where these grants are essentially string-free, their appointment letters from HR expressly gives them this right and the terms and conditions of the grants do not preclude it. School / Divisional / Departmental authorisation for such activity is given on a case-by-case basis by approval of the RG form for the grant in question.

e) Honorary appointments

People with honorary appointments are permitted to act as a named co-lead investigator or co–investigator on awards where they have a permanent member of King's staff acting as a co-lead on the project who will be in a position to take responsibility to the funder on behalf of King's for successful completion of the project.

In addition, and in furtherance of the academic mission of King's Health Partners, there are certain circumstances where a KHP NHS Trust employee may be permitted to act as a lead investigator.

There has to be strong academic merit and no financial, regulatory or legal impediments or disadvantages to King's. Funding mechanisms of some schemes (e.g. certain EU schemes) may not make them viable to King's, nor may certain terms and conditions be acceptable to the College and in both cases, such awards will need to run through the employing KHP NHS Trust. Decisions about which individuals and which of their projects may be handled in this way will be made strategically.

This policy principally relates to Research Council and charitable grants, rather than to contracts, because contracts present potentially problematic issues (see Section 8, part 30 for full details).

Research Council FEC grants will not yield the normal King's level of overall overhead recovery where investigators are not King's employees, because only King's employees' time can be costed on projects as Directly Allocated time. Indirect and Estates Costs are recoverable on such grants, however.

In order for King's to accept awards or submit applications on behalf of KHP NHS Trust staff wishing to act as a King's lead investigator:-

- There must be formal written approval by the relevant KHP Trust at an appropriately high level (e.g. Head of the Trust R&D Office); this could be either on a case-by-case basis, or by a well-defined, blanket agreement relating to certain kinds of award that may held by specific individuals.
- The individuals are officially assigned to a King's School and Research Division.
- There is formal approval by the relevant Head of School and Research Division; this is important as there are significant risks attached to non-King's employees acting as sole investigators on grants (e.g. if sanctions are applied by a Research Council or payment withheld).

In addition, where a KHP individual holds an award at King's as the lead investigator, Financial Regulations and Procedures regarding the sign-off of expenditure require approval by a permanent member of King's staff.

Should a KHP individual wish to be a sole authorising financial signatory, this requires the express written permission of:

- the Head of School,
- the Head of School Division and
- the Chief Accountant.

Where a KHP individual is a co-investigator on an award at King's, a substantive member of King's staff will be required to countersign financial transactions.

Where it is agreed that awards may be operated through King's on the basis set out above, those awards must be made to King's directly in the case of new projects. In the case of existing projects, subcontracted or novated to King's from the relevant KHP NHS Trust with the funders' express consent.

f) Fellowships

Where a research fellowship is awarded to develop the career of a King's researcher, although that researcher may not hold the award solely in his/her own name unless he/she is a permanent member of staff, King's actively encourages the researcher to be identified as the co-lead investigator or co-investigator to help raise their academic profile and further their academic career.

See Staff employed on fixed term contracts which would be applicable for fellows funded for the period of the fellowship.

2. Funder rules on eligibility

Please check the rules of the particular funding scheme. There are often criteria concerning a person's career experience and employment status (particularly fellowships), funding ceilings and subject matter etc.

Where the funder lays down particular eligibility criteria for a person for a specific funding scheme, and where King's is willing to accept these criteria, they will take precedence over, or supplement, existing King's policies for that particular scheme and / or application only.

3. External project staff and consultants

Following award, the Pre-Award Team will negotiate contracts with all external parties to flow funding and appropriate award terms and conditions to those parties.

The payment of consultancy fees to King's academic staff from research projects raises issues of financial control, transparency, academic reputation and conflicts of interest, as well as questions about what work such payments would relate to that the individual was not already obliged to carry out under the research agreement as part of their employment duties. Therefore no consultancy fees may be paid directly to King's employees from research project budgets.

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E. STUDENT-BASED RESEARCH PROJECTS

Some funders have contractual terms which are not compatible with using a student on their projects (e.g. as regards a student's need to submit and publish his/her thesis). The Pre-Award Team can advise you when this may apply and, if appropriate, negotiate with funders to make sure that their terms are compatible with students' requirements. RG&C also require that contracts which support students are either for the full three year duration of their studentship and/or that your School has measures in place to ensure that the student can be supported financially for the full duration of their course.

You should be aware that as students are not legally employees of King's, they cannot be instructed and directed in the same way that an employed researcher can. Their prime purpose is to undertake a course of study leading to a higher degree and they cannot be required to produce directed, defined research deliverables. This again makes their use on certain kinds of contract inappropriate.

There are also specific publication requirements on student-based projects which should be taken into account when dealing with funders, for example the requirement to submit a thesis.

Indirect Costs ('Overheads')

To recognise the unique academic value of research students, King's does not charge indirect costs on bona fide philanthropic studentships provided that there are no strings attached to the support and, for example, it is outside the scope of VAT. However, the purpose of a true 'studentship' should be to provide funding for a student to pursue his/her studies rather than to undertake directed work for an organisation that also requires a significant stake in any intellectual property generated – this is not a studentship, but a straightforward contract.

In the event that a student is to be supported on a contract in this way, because the student is essentially a research worker, his/her costs will include overheads in the same way as any other research worker. Hence indirect costs should be charged on the student's stipend, although Pre-Award will be mindful in each case of all the factors involved which should affect the level of indirect costs to be charged (e.g. if a student is paying overseas fees).

In the contract that is negotiated to support the student, the literary copyright in the student's thesis will not be assigned to the funder.

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F. KCL INFO (POLICIES, BANK DETAILS, CHARTER ETC.)

Establishment

- Registered address for King's College London: Strand, London, WC29 2LS
- VAT registration number: 627403551
- Data Protection registration number: Z7915194
- Charter, Statutes and Ordinances
- King's by numbers, including dates
- Profile 2014 - giving student and staff numbers

Policies and regulations

- Policy Zone - to search current policies
- Regulations - Regulations approved by the College Council, or by the Academic Board or the Finance Committee under delegated authority from the Council. Includes Regulations on/relating to: Academic conduct, Students, Finances, HR, IT and Library Services
- Equality and Diversity Policies, Statements and Guidance
- Environmental and Sustainability Policy
- Health and Safety Policy
- Data Protection Policy
- Freedom of Information Policy
- Records and Information Management Policy
- Academic Honesty and Integrity Policy
- Research Misconduct Policy and Procedures
- Treasury Policy - please contact the Treasury Accountant for the most up to date policy

NIH grants

There are specific requirements for applicants and King's around financial conflicts of interest. To comply with NIH requirements, King's has implemented procedures, which are detailed in a later section.

Financial information

Financial Statements - showing total income, as well as research income. If a funder requires accounts to be included in a proposal or tender, attach the Financial Statement(s) or quote the webpage, which is publicly accessible.

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G. HUMAN PARTICIPANTS & HUMAN TISSUE

1. Studies that involve human participants

Ethics approval

Any studies that involve human participants in any capacity (e.g. social surveys, healthy volunteers or patients) must have approval from the appropriate Research Ethics Committee.

Personal data

In addition, where personal data is to be collected and used:

- Participants must consent fully and freely to the use and reuse of their personal data.
- Identifiable data can only be reused for secondary research under certain conditions; if you are unsure, seek advice.
- Personal data should usually be anonymised and should only be published in identifiable form with consent.

Research data may have ongoing value beyond a single study. Data can be retained for research purposes in compliance with the *Data Protection Act 1998,* although certain conditions apply. Misuse of personal data by researchers is a serious offence under the Act and is also a breach of King's regulations. Applicants are required to make appropriate declarations regarding the involvement of human participants in their RG Form.

Accepting an award that requires ethics approval

If a project requires ethical approval from the outset, a copy of the REC number and approval date is required by the Pre-Award team in order for them to formally accept the award.

Insurance

If the nature of a clinical study is outside of the insurance cover held by King's, additional cover will need to be obtained, at additional cost.

2. Studies that involve human tissue

Where researchers intend to use human tissue they must have full ethical approval and Participant Informed Consent Forms in place.

A key consequent of the *Human Tissue Act* was to make the giving of informed consent the fundamental principle underpinning lawful storage and use of human bodies, organs and tissue and this applies to the storage and use of tissue from living people as well as the taking, storage and use of tissue from the dead.

Consent for research is not a legal requirement if:

(i) the samples are anonymised to the researcher and

(ii) the research has been approved by a suitable Research Ethics Committee.

It is illegal even to hold "bodily material" (i.e. material consisting of or including human cells such as hair, blood, nail and gametes) with the intention of undertaking DNA analysis on it without consent.

Unless these exceptions apply, if there is any intention of carrying out genetic analysis on identifiable material, consent for this must be obtained at the time the sample is taken.

Extracted DNA and RNA where no whole cells remain is not classed as "bodily material".

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H. NHS STAFF, FACILITIES, PATIENTS & PATIENT DATA

NHS Trusts and universities can take a considerable amount of time to produce costs for a proposal, so it's advisable to contact these parties early on. Contact NHS Trusts if the project involves NHS Trust staff, facilities, patients and/or NHS patient data and any of these resources may have a cost associated with them for your study.

To obtain costs from KHP NHS Trusts, you will need to send them a detailed description of the proposed project.

Guy's & St Thomas' NHS Trust require 6 weeks notice to process an application, which includes providing costs and obtaining approvals from senior Trust staff.

King's College Hospital NHS Trust require at least 4 weeks notice.

SLAM / IOP office should be contacted as soon as possible.

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I. RESEARCH DATA MANAGEMENT

Increasingly funding bodies are asking for detailed information on:

1. what research data is going to be created,
2. how research data is going to be managed beyond the end of a project (in terms of sharing and preservation), and
3. what are the costs of managing that data.

Some funders are providing funding towards those costs.

The Information Management team have created Research Data Management pages to provide information and advice on managing research data. Please contact the team concerning any aspect of data management (including advice on the cost of data management). Their email address is research.data@kcl.ac.uk.

Data Managment Plans

For advice on writing data management plans (as well as talking to the Information Management team) you may find the following resources useful (in addition to talking to the Information Management team):

1. DCC's pages on data management plans
2. MRC template Data Management Plan

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J. NIH CONFLICTS OF INTEREST REQUIREMENTS

1. Overview

This Section covers the procedures adopted by King's regarding applications to and awards from NIH concerning NIH Financial Conflict of Interest ('FCOI') policy. The procedures can be downloaded from here and are summarised below.

With effect from August 1st 2012, the NIH implemented a new set of policies relating to conflicts of interest applicable to organisations where they fund research. The policy and extensive guidance has a FAQ section which is a useful guide through the requirements.

The policy applies to everyone responsible for the design, conduct or reporting of research funded by the NIH i.e. Principal/Co-Investigators, honorary staff, students, technicians, external collaborators, consultants etc. All these individuals are referred to in these notes and the policy as Investigators.

The policy applies to work funded by the NIH itself, NIH institutes and the Public Health Service of the US Department of Health & Human Services.

To comply with the policy, King's has implemented procedures to be followed by those involved in an NIH application or award, and by their associated Heads of Division/Department and local administrative managers.

The NIH policy is supplementary to the College's existing policies, procedures and guidelines on related matters such as Conflicts of Interest and Good Practice in Academic Research.

Definition of a Financial Conflict of Interest under NIH policy

An FCOI exists when, after investigation, King's reasonably determines that a person has a 'Significant Financial Interest' ('SFI') that is related to an NIH-funded project and that could directly and significantly affect the design, conduct or reporting of the NIH-funded research. SFIs that do not directly and significantly affect the design, conduct or reporting of the NIH-funded research are not FCOIs.

A SFI is a financial interest consisting of one or more of the following interests of an Investigator (and those of an Investigator's spouse and dependent children), that reasonably appears to be related to the Investigator's King's responsibilities (research, teaching, committee membership, professional practice etc):-

- For any publicly traded entity*, an SFI exists if the value of any remuneration received in the 12 months preceding the disclosure and the value of any equity interest as of the date of disclosure, when aggregated, exceeds US$5,000.
- For any non-publicly traded entity*, an SFI exists if the value of any remuneration received in the 12 months preceding the disclosure, when aggregated, exceeds US$5,000, or when the Investigator (or Investigator's spouse or dependent children) holds any equity interest.
- Intellectual property rights and interest (e.g. patents and copyright) on receipt of income related to such rights and interest.

* In the policy 'entity' means any domestic or foreign, public or private organisation (excl. US Federal/gov agency) from which an investigator (and spouse and dependent children) receives remuneration or in which any person has any ownership or equity interest.

In addition, as SFIs, Investigators must also disclose the existence of any travel related to their King's responsibilities that is reimbursed or sponsored by commercial funders. This includes travel paid on behalf of an investigator and not reimbursed to the Investigator, so that the exact monetary value may not be readily available. This does not include travel which an investigator claims through the King's system for claiming expenses and is charged to a research project.

2. Investigator responsibilities

a) Disclosure of Significant Financial Interest within NIH timescales. Failure to disclose will result in additional reporting to the NIH. Investigators must make initial (no later than at the time of

application), on-going (within 30 days of discovering/acquiring a new SFI) and annual returns for the life of a project, even if annual returns are 'nil' returns, via their Divisional/Departmental Administrator/Business Manager (hereinafter collectively 'Administrator(s)').

b) Principal Investigator to collect SFI disclosures of Investigators at other institutions, where King's has or will subcontract institutions whose staff are to perform part of the project, and forward to their Administrator to report to the NIH within set timescales.

c) Prompt disclosure of any bias found in the design, conduct or reporting of a project to the Head of Division/Department, Administrator and Director of Research Grants and Contracts.

d) Compulsory completion of the NIH online tutorial. All investigators must complete the online NIH FCOI tutorial at the application stage and at least every four years. Investigators new to the College must complete training even if they have done so elsewhere within a four year period. There are additional training requirements depending on individual circumstances.

e) Disclosure of FCOIs in each public presentation of the results of a project (and as an addendum to previously published presentations) for any FCOI not properly managed or reported by an investigator for a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment.

f) Adherence to the agreed Management Plan in case of any identified Financial Conflict of Interest and adherence to any other requirement of the NIH and College concerning FCOI.

Non-compliance must be reported to the NIH.

3. Division/Dept'al Administrator/Business Manager responsibilities

a) Co-ordination, collection and submission of FCOI reports within NIH timescales. King's is required to submit initial (no later than at the time of application for research funding), on-going (within 30 days of an investigator discovering or acquiring a new SFI) and annual reports throughout the full duration on an NIH project. Annual returns are required to be submitted at the same time as the project annual progress report (though FCOI declarations are submitted separately through eRA Commons).

b) Forwarding declared SFIs to the Head of Division/Department for them to determine whether a declaration constitutes an FCOI. For investigators in different Divisions/Departments to the lead investigator, declarations should be sent to the Heads of both to jointly determine any FCOI. 'Nil returns' (i.e. returns with no declared SFIs) are not submitted to the Head of Division/Department.

c) Inclusion of FCOIs for collaborating institutions in 1. and 2. above. Where the College has subcontracted another institution for their investigators to be involved in a project, the Principal Investigator should supply copies of declarations for those investigators for a) inclusion in Administrator reports to NIH and b) inclusion of declared SFIs in SFIs forwarded to Heads of Division/Department.

d) Promptly forward positive FCOI returns to Director of Research Grants and Contracts for review and further action i.e. declarations that have been determined as being FCOIs by the Head of Division/Department. Further action will include additional reporting to the NIH.

e) Maintaining all FCOI-related records for a project for at least 3 years from the date a final expenditure report is submitted to the NIH, or such other timescale as specified by the NIH. Records include those relating to the reviews of FCOIs.

NIH user guide to submitting SFI/FCOI reports through eRA Commons.

4. Head of Division/Department/School responsibilities

a) Role of the Head of School

Where an Investigator is also a Head of Division/Dept, references below to the Head of Division/Dept should read Head of School.

Where an Investigator is also a Head of School, the Director of Research Grants & Contracts will work with the Head of School and Administrator to identify a suitable individual capable of reviewing the SFI declarations of the Head of School.

b) Determining whether an SFI declaration constitutes an FCOI

On receipt of SFI (Significant Financial Interest) declarations forwarded by Administrators, Head of Divisions/Depts are responsible for determining whether an SFI declaration constitutes an FCOI due to (i) the impact on the NIH-funded project or (ii) the outcome the NIH-funded project may have on the SFI.

Where an SFI has been declared for an Investigator in a different Division/Dept to the Principal Investigator, the Heads of both Division/Dept are to jointly determine any FCOI and work on the development of a Management plan.

If there are Investigators at other institutions, where the College has subcontracted work, SFI Declarations for these individuals will also be forwarded to the Head of Division/Dept of the College PI for determination.

c) Managing FCOIs

Where it is determined that there is an FCOI, the Head of Division/Dept will instruct the Administrator to pass details to the Director of Research Grants & Contracts for review and further action. Such action will include reporting to the NIH and working with the Investigator and Head of Division/Dept to develop and implement management plans to ensure the FCOI is appropriately dealt with and controlled within NIH specified timescales; this includes completion and submission of a formal Management Plan.

The Head of Division/Dept is responsible for monitoring Investigator compliance with Management Plans until completion of the project. Non-compliance with the Management Plan must be reported to the NIH.

In the event that a bias is identified in the design, conduct or reporting of a project, the Head of Division/Dept and Director of Research Grants & Contracts will promptly notify NIH and take such other necessary corrective actions. In the case of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment, corrective actions will include Investigators being required to disclose FCOIs in public presentations of the results of the project.

In the case of non-compliance with NIH and King's policies by a King's-employed Investigator, the Head of Division/Dept should take appropriate disciplinary actions.

d) Reporting to NIH via Administrators

The Head of Division/Dept should inform Administrators on all of the above so that they can submit the required information to the NIH within NIH timescales.

5. Investigator Pre-Submission Declaration Form

To comply with NIH policy, an NIH Pre-Submission Declaration Form is required to be completed and submitted to RG&C prior to their giving approval for an NIH application to proceed and/or approval for King's staff to be involved in another institutions' application.

To that end, please send the following documents 5 days before the date you intend to submit the application:

- a copy of the application form
- an internal RG form
- a signed NIH Declaration Form for each King's Investigator
- a signed NIH Declaration Form for each external investigator, at institutions to receive subcontracts from King's following award

6. Forms

a) Pre-Submission (of an application) Declaration Form
b) SFI Disclosure Form
c) Retrospective Disclosure Form
d) FCOI Management Plan

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K. APPROVAL & SUBMISSION STEPS

All applications, official quotations and tenders, where any amount of funding will come to King's (including where other institutions are leading a project) must be approved by RG&C prior to submission.

Approval for a tender

Please forward the funder's tender documentation to RG&C early on, for them to review the requirements, which typically include a requirement to accept funding terms and conditions at the submission stage.

It's common for there to be issues with the terms and conditions as they're unlikely to include terms enabling King's to publish research results or use results for future research (both important factors in determining whether work can count as research).

In practice, RG&C provide wording (usually in the form of a letter) to include with a tender response outlining *"the potential terms and conditions that King's would wish to discuss should the tender be successful*."

From experience, many funders are receptive to requests for contractual changes.

Approval for a grant application

1. Send a completed internal RG form and a copy of the final proposal to RG&C at least 5 working days before the date you intend your proposal to be sent to the funder.
2. On a first-come-first-served basis, RG&C check each application and consult with applicants to resolve errors / issues with the contents (incorrect figures and missing attachments are common errors). Online (e.g. RCUK je-s applications) and paper applications may be returned to applicants to revise.
3. Once checks and revisions are complete, RG&C authorise applications for submission to funders. For online submission systems, authorisation is often the *submitting step*. For paper forms, RG&C sign as *Finance Officer, Institutional Official* or equivalent.

R&D authorisation

If R&D authorisation is required (e.g. NIHR applications for trials) and King's is sponsoring the study (in terms of ethics sponsorship), then you will need to contact Keith Brennan as the King's signatory.

If King's is not the sponsoring institutions you will need to contact the relevant institution's R&D office to obtain their signature.

Awards acceptance and contract signatories

Once awarded, the RG&C can accept grants on behalf of King's. Contracts, however, must be signed by the Director of Research Grants and Contracts or the Head of Pre-Award.

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L. INFORMATION NOT ELSEWHERE

1. Researcher skills training

For wording on skills training please contact Professor Vaughan Robinson in the Graduate School

2. Intellectual Property

The IP & Licensing Team can advise on intellectual property matters.

In addition, RG&C are responsible for negotiating terms and conditions on intellectual property with funding bodies, collaborators, subcontractors and consultants.

3. Writing a winning proposal

In a competitive environment, applications need to be outstanding for funding to be awarded.

Advice on grant writing:

- Research funding: 10 tips for writing a successful application (Guardian article)
- Points to bear in mind when preparing a grant application (Wellcome Trust advice).
- Make sure your project is relevant to the funder and specific funding call.
- Read and carefully follow all guidance, recommendations and rules of a funder.
- Arrange peer review by respected academics in your field. Funders typically use peer review in deciding awards and, by having already addressed any weaknesses identified by pre-submission peer review, your application will have a better change of success.
- Allow enough time to prepare and submit a high quality proposal. Most applications, when checked by the Pre-Award team, are found to require revision (e.g. because required information is missing or incorrect).

End.