



Research Management & Innovation Directorate

Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards Policy & Procedures

Issuance Date:	01/08/2023
Effective Date:	01/08/2023
Scope:	This policy addresses the disclosure and management of financial conflicts of interest. It applies to all research funding applications, grants and agreements issued by the US government Public Health Service and any organisation under its control such as the National Institutes of Health (NIH) and all of its 27 constituent Institutes and Centers . This policy applies when King's College London is the sole or lead organisation, a subrecipient, subcontractor or any other form of third party on the research project.

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1. Summary

The United States Federal Department of Health and Human Services (HHS) has determined, pursuant to 42 CFR. Part 50, Subpart F and 45 CFR. Part 94, as revised on August 25, 2011, that effective no later than August 24, 2012, Public Health Service (PHS)- funded Investigators shall be subject to specific requirements regarding the disclosure and management of conflicts of interest with regard to research in order to provide a reasonable expectation that PHS-sponsored research will be conducted free of bias resulting from Investigator financial conflicts of interest.

This Financial Conflict of Interest policy applies to any funder which is legally linked to the PHS, such as the National Institutes of Health (NIH), and any other funder which has adopted this policy. This policy describes procedures which any Investigator and Institution applying to, or receiving funding from, a funder this policy applies to must follow and implement. The NIH has extensive [guidance and supporting material](#) available relating to this policy and as such this King's College London policy widely uses and refers to the NIH in much of the source information; some non-PHS funders adopting this policy may deviate in certain requirements or processes.

This policy is supplementary to, and should be followed in conjunction with, King's College London's own policies, procedures and guidelines on related matters, such as the [Disclosure of interests Policy and Procedures](#), [Academic Honesty & Integrity Policy](#), the [External Funding & collaboration Policy](#), [Financial policy and Procedures](#) and the [Fraud, Theft, Bribery and Corruption policy](#).

For projects led by King's College London, this policy may also apply to any external organisations, such as subawardees, subcontractors, external consultants or any other third party if they do not have their own PHS compliant financial conflict of policy. Where necessary, King's College London will include applicable terms requiring adherence to this policy in the agreements that King's College London places with these organisations and individuals. As mandated by this policy, it can be accessed externally on this King's College London webpage: <https://www.kcl.ac.uk/research/funding/applications>

In addition, all supporting documentation related to this policy can be found on this internal webpage: <https://internal.kcl.ac.uk/innovation/grants-contracts/pre-award/funding/nihfcoi>

2. Definitions and descriptions under this policy

'Designated Institutional Official': It is a requirement under this policy for the Institution to identify persons to act in the capacity of 'Designated Institutional Official'; it is a role that can be assigned to multiple people. The role is to have oversight and authority to carry out required actions under this policy and to report and be accountable to the funder for matters related to this policy.

'Financial Conflict of Interest (FCOI)': In terms of the PHS policy, an FCOI exists when, after investigation, King's College London reasonably determines that an Investigator has a Significant Financial Interest ('SFI') that is related to a PHS-funded research project (or a project

for a funder which has adopted this policy) and that could directly and significantly affect the design, conduct or reporting of the funded research. SFIs that do not directly and significantly affect the design, conduct or reporting of the PHS-funded research are not FColS.

'Investigator': An 'Investigator' for the purpose of this policy is defined as any individual responsible for the design, conduct, or reporting of the results of work performed or to be performed under the PHS-funded project (or a funder which has adopted this policy). This includes the Principal Investigator, Co-Investigators, Collaborators, Consultants, and any other individual who has responsibility for designing, conducting, or reporting of research funded by PHS or proposed for such funding (such as Postdoctoral researchers, technicians or research support staff).

'Investigator's Institutional Responsibilities': Institutional responsibilities means an Investigator's professional responsibilities on behalf of King's College London, and includes activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

'Management Plan': a Management Plan will be required to implement the management of identified FColS under this policy. The management plan, as a minimum, shall comprise of: i) the roles and principal duties of the affected Investigator(s); ii) how the plan will safeguard objectivity in the affected research activities; iii) conditions of the plan; iv) how the plan will be monitored; v) agreement from the affected Investigator(s).

'Public Health Service (PHS)': the PHS is a collection of agencies of the [US government Department of Health and Human Services](#). The PHS operating agencies includes the [National Institutes of Health \(NIH\)](#), which itself is comprised of 27 Institutes and Centres focused on different areas related to human health. Other PHS controlled operating agencies include the Foods and Drugs Administration (FDA) and the Centers for Diseases Control and Prevention (CDC).

'Senior/key personnel': for this policy 'Senior/key personnel' means the Principal Investigator or Co-Investigator(s) of the grant/application and/or identified as such in the progress report or any other report submitted to the funder by the institution as part of this policy.

'Significant Financial Interest (SFI)': Consistent with the United States Federal regulations (42 CFR Part 50.603 and 45 CFR Part 94.3), SFI means a financial interest consisting of one or more of the following interests (A-E) of the Investigator or the Investigator's spouse, civil partner or other person generally recognised as their domestic partner, and dependent children that reasonably appears to be related to the Investigator's institutional responsibilities. For this policy monetary values are represented in US Dollars and are indicative values only; any appropriate exchange rate can be applied for the approximate Sterling/GBP value:

- A. With regard to any publicly-traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure *and* the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For this definition, remuneration includes salary (other than salary described in Paragraph E, below), consulting fees, honoraria, and the equity interest value at the

date of disclosure as determined by public prices or other reasonable measure of fair market value.

- B. With regard to any non-publicly-traded entity, an SFI exists if the value of any remuneration (other than remuneration described in Paragraph E, below) received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse, registered domestic partner, or dependent children) holds any equity interest (e.g. stock, stock option or other ownership interest).
- C. Intellectual property rights (e.g. patents, copyrights) and interests, upon receipt of income during the 12 months preceding disclosure from such rights and interests. SFIs, however, do not include royalties received from King's College London.
- D. In the case of travel, sponsored travel or reimbursements made to or on behalf of the Investigator, regardless of amount, by a for-profit or non-profit entity related to the Investigator's Institutional Responsibilities. SFIs, however, do not include travel reimbursed or paid by a US federal, state, or local government agency, a UK local or central government agency, a UK or US institution of higher education, or a research institute, academic medical centre or hospital affiliated with an institution of higher education.
- E. The term "Significant Financial Interest" does not include the following types of financial interests:
 - I. Salary, royalties, or other payments made by King's College London (including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights) to a King's College London Investigator who is currently employed or otherwise appointed by King's College London;
 - II. Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a federal, state, or local government agency, a UK local or central government agency, a UK or US institution of higher education, or a research institute, academic medical centre or hospital affiliated with an institution of higher education.
 - III. Income from investment vehicles, such as mutual funds and retirement funds, in which the Investigator does not directly control investment decisions.

3. Investigators' Responsibilities and actions

The definitions of 'Investigator' and 'Investigator's Institutional Responsibilities' under this policy are described in section 2. Investigators' main responsibilities under this policy are:

1. Accurate and timely completion of the 'PHS Financial Disclosure and Assurance' form. This form should be completed by anyone meeting the description of 'Investigator' when applying for funding through King's College London (whether as the project lead or a partner, including as a subrecipient, subcontractor, third party or external consultant) and attached to the Worktribe project at the latest at 'Bid Approval' stage.

In circumstances where this does not apply such as when a new member of staff meeting the definition of 'Investigator' is employed on the grant or a new Investigator transferring to King's College London, this should be completed as soon as possible and no later than the Investigator commencing their time on the grant at King's College London. For awarded grants this form should be completed annually, which usually corresponds to the new project budget period (grant renewal). All completed and signed forms should be uploaded to the Worktribe project 'Documents' tab. The form is available to download on [this internal webpage](#).

2. All Investigators must complete the online NIH FCol tutorial ([hosted on this webpage](#)) prior to engaging in research related to any grant covered by this policy and at least every four years. Investigators who are new to King's College London must complete the tutorial even if they have done so within a four-year period at a previous organisation. It is recommended that all investigators covered by this FCol policy complete this online training even if they are not being funded by the NIH. The course 'Certificate of Completion' should be uploaded to the Worktribe project and kept on record by the Investigator.
3. All Investigators must promptly disclosure (and within 21 days) of a new FCol which was not otherwise declared in the requirements of point 1 above. The Investigator should complete a new 'PHS Financial Disclosure and Assurance' form and upload this to the Worktribe project 'Documents' tab and alert the Pre-award liaison of the form. This will then trigger further actions as described in section 4.2 'Institutional Responsibilities and actions carried out by Research Grants & Contracts'.
4. When any SFI covered by this policy is identified (that is a 'Yes' answer to any applicable question in the 'PHS Financial Disclosure and Assurance' form) the Investigator shall provide further details by completion of a 'Full Disclosure of Significant Financial Interests' form which will be supplied by a member of Research Grants & Contracts (RG&C). Upon review by RG&C and any subsequent review by the 'FCol committee' of the details provided, if an/any FCol(s) is/are identified the Investigator should cooperate with RG&C (and as applicable the 'FCol committee') as the 'Designated Institutional Official' in implementing a Management Plan.
5. As a specific clause of this policy for the NIH, for any FCol not properly managed or reported by the Investigator for a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment, the Investigator must disclosure the FCol(s) in each public presentation of the results of a project (and as an addendum to previously published presentations).
6. For the avoidance of doubt, this PHS FCol policy is separate to the King's College London [Disclosure of Interests Policy and Procedures](#); in instances where there is overlap (overlapping FCol(s)) the Investigator should treat the policies as separate in terms of any requirements mandated by the policies. While the FCol(s) can be managed together where appropriate, this PHS FCol policy, and all King's College London policies, must be complied with if there are separate actions to be followed.
7. All Investigators, and particularly grant Principal Investigators, should ensure that any new staff covered by the definition of 'Investigator' under this policy are made aware of the policy and procedures to follow.

8. All Investigators covered by this policy acknowledge that failure to disclose relevant information required under this policy may result in King's College London, as the signatory to the funder's or project lead's grant/agreement or (sub)contract, being in breach of the funder's terms and conditions and this may result in the grant being terminated and/or sanctions applied. Under this policy all Investigator non-compliance must be reported to the NIH via the 'Designated Institutional Official' (as detailed in section 4.2).
9. In addition to point 8, failure to disclose SFIs, properly manage any identified FCol or any other failure to adhere to the procedures of this policy may result in the Investigator(s) being referred to the relevant King's College London [discipline procedures](#) and/or be considered a case for research misconduct.

4. King's College London institutional responsibilities and actions

4.1 Department/School/Faculty responsibilities and actions

1. The Department/School/Faculty, particularly any Professional Services staff directly supporting or managing Investigators applying for funding or holding funding covered by this policy, should be familiar with section 3 of this policy; 'Investigators' responsibilities and actions'. In particular the Department/School/Faculty should have oversight to ensure that all forms required to be completed under this policy by the Investigator(s) are done so and uploaded to Worktribe as required.
2. The Department/School/Faculty should address the requirements of this policy alongside the other related King's College London policies, particularly the [Disclosure of Interest Policy & Procedures](#).
3. In order to assist with any SFI which needs assessment to determine if they constitute a FCol under this policy, the Department/School/Faculty may be required to assist the King's College London Designated Institutional Official(s) and/or the 'FCol committee' with the internal processes. As appropriate, this is likely to require assistance from the Investigator's Line manager, Head of Department (to assist the 'FCol committee') and/or a senior research manager within the Department/School/Faculty.
4. For any SFI which is found to constitute a FCol under this policy the Department/School/Faculty may be required to assist the King's College London Designated Institutional Official(s), along with the Investigator and as appropriate the 'FCol committee', to develop, implement and monitor a Management Plan. If a Management Plan is established, the Department/School/Faculty acknowledges that they will need to take oversight of the implementation and monitoring of the plan, as appropriate, and as agreed in the Management Plan itself.
5. If the Department/School/Faculty become aware of an Investigator failing to disclose required FCol or failing to adhere to the implementation of a Management Plan they should contact the King's College London Designated Institutional Official or the grant King's College London Pre-Award liaison as soon as possible, and within no more than 21 days. If this contact information is not readily available, they should email usresearch@kcl.ac.uk bearing in mind that this is a shared inbox and so any correspondence should be marked as 'Confidential'.

6. The Department/School/Faculty acknowledge that in cases where the Investigator has failed to disclose any SFIs, failed to properly implement the Management Plan and/or failed to comply with any other aspect of this policy they may be required to action or assist with any disciplinary reporting, including any resulting actions and processes.

4.2 Institutional responsibilities and actions carried out, or coordinated, by Research Grants & Contracts

The Research Grants & Contracts (RG&C) Division within The Research Management and Innovation Directorate (RMID) has the institutional responsibility of 'Designated Institutional Official'. Most actions will be carried out by the Pre-award International team, with support from other members of RG&C as required. Beyond the role of Designated Institutional Official, RG&C are responsible for ensuring that this PHS compliant Financial Conflicts of Interest policy is kept up to date, including all of the supporting documentation and guidance. The remit also includes the following:

1. Monitoring of compliance with the Investigator's responsibilities on SFI/FCoI disclosure and triggering the appropriate processes once an Investigator discloses potential or actual FCoIs according to this policy. As 'Designated Institutional Official' they will lead on collecting further information to identify if an FCoI exists; this includes requiring the appropriate Investigator(s) to additionally complete the 'Full Disclosure of Significant Financial Interests' form. The form can be downloaded [from this internal webpage](#) for reference.
2. On completion of the 'Full Disclosure of Significant Financial Interests' form, where required, RG&C will review the details and determine if a meeting of the 'FCoI committee' is required (that there is sufficient evidence to support the need for a 'FCoI committee' meeting to review the SFI(s)). If a meeting is required, a member of the Pre-award International team (Senior Research Funding Associate) will organise and secretariat the meeting. Meetings shall consist of the following positions within King's: 1) Director of Research Grants & Contracts; 2) Vice Principal Research & Innovation; 3) Chief Compliance Officer; 4) Head of Department of the affected Investigator(s). For each position, a suitable deputised role can act as replacement in lieu. Should any further information be needed from the Investigator(s) prior to, or after the 'FCoI committee' meeting, the Investigator(s) should cooperate with any such request. The purpose of an FCoI Committee meeting is to determine if one or more SFIs exists, and to identify recommendations for any remedial actions to be taken as part of a Management plan. Timings of committee meetings will need to comply with the general timelines as detailed in point 4.2.6 below. As such, an FCoI Committee will usually meet no later than 30 days after a SFI is initially disclosed.
3. If on completion of the above (whether a 'FCoI committee' meeting took place or not) it is found that the Investigator(s) does not have any FCoI(s) to manage, they will be issued with a 'Significant Financial Interests review outcome (no FCoIs)' form detailing the reasons of the review decision.
4. Where any FCoI exists, RG&C will initiate and facilitate requirements for a Management Plan to be designed and implemented (to include any recommendations from the FCoI

committee meeting as applicable), including suggestions for managing the FCol(s). The Department/School/Faculty may be required to assist with this process. The design, implementation and monitoring of the FCol will be appropriate to the nature of the FCol and in context with the relating research grant and role of the Investigator(s). The Investigator(s) with the FCol(s) takes overall responsibility for implementation of the Management Plan. The Department/School/Faculty takes responsibility for the local monitoring of the Management Plan unless otherwise stated and agreed in the Management Plan itself.

5. Where it is identified that a SFI was not disclosed or reviewed in a timely manner, RG&C shall within 60 days review the SFI to determine if an FCol exists, and if so, implement an interim Management Plan. A retrospective review should also be carried out as specified in point 4.2.9 below.
6. Where King's College London is a grant subrecipient, subcontractor, or the Investigator is acting as an external consultant, on an award issued by the funder to another institution (the project lead, referred to as the 'Prime' by the funder), the Pre-award International team will ensure that the project lead is notified of the FCol and any agreed Management Plan according to any timescale mentioned in the subaward or other applicable agreement. This is to allow the project lead to fulfil their requirement under the policy to report the FCol to the funder. For any new FCol identified, the project lead is required to report the FCol to the funder within 60 days of the disclosure of the FCol by the Investigator; the Pre-award International team should therefore be notified as soon as possible once a SFI is to be disclosed, and no more than 21 days in order to meet this obligation. Note that King's College London does not report FCol directly to the funder when not the project lead.
7. Where King's College London is the project lead (Prime), the Pre-award International team will lead on and coordinate implementation of compliance of the PHS policy by any subrecipients, subcontractors, external consultants or other third parties. Any subrecipient, subcontractor, external consultant or other third party may either use their own PHS compliant FCol policy or follow this policy and any agreement issued by the Pre-award International team will include this provision.
Note, regardless of which PHS compliant institutional policy is used, all FCol reporting to the funder is done by the lead organisation; whether or not the FCol is for their staff (Investigators) or any other external party (including any subrecipient, subcontractor, external consultant or other third party). The agreement/contract with King's College London shall detail the requirements for compliance.
8. RG&C will act as the 'Designated Institutional Official' for King's College London and will report FCol as required by the funder (which are detailed on this [NIH webpage](#)). The NIH requires that the lead organisation reports FCol as follows: i) before the funding for any new award is expended for FCol that were disclosed by the Investigator(s) at the time of application or at the Just-In-Time stage; ii) within 60 days of a new FCol being disclosed by an Investigator; iii) annually at the time of the annual financial and scientific reporting (progress report) for existing FCol until the end of the grant or the FCol no longer exists, whichever is earlier.
9. The policy mandates certain actions in cases of non-compliance: In addition to those detailed elsewhere in this policy, there is a requirement for a retrospective review.

Whenever an FCol is not identified or managed in a timely manner, including by the investigator to disclose an SFI, failure by the Institution to review or manage an FCol, or failure to comply with the Management Plan, RG&C shall within 120 days of the determination of non-compliance complete a Retrospective review of the Investigator's activities and the project to determine bias in the design, conduct or reporting of such research. Where bias is found, a Mitigation Report shall be promptly submitted to the funder. If found to be warranted from the retrospective review, the previously submitted FCol report should be updated. Subsequent FCol reports are then submitted annually. In compliance with this policy the Retrospective review shall include as a minimum: the project number and title, name of the (main) project Principal Investigator, name of the entity with which the Investigator has an FCol, reasons for the retrospective review, detailed methodology used for the review (e.g. methodology of the review process, the staff involved and any documentation reviewed), findings and conclusions of the review.

5. Further requirements under this policy

1. Record retention

Records of financial disclosures and the institutional review of, or response to such disclosures, whether or not a disclosure resulted in the determination of a FCol, and all actions under this policy or Retrospective review shall be maintained for at least 3 years from the date of submission of the final expenditure report, or for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, respectively, as reported to the HHS awarding agency or pass-through entity (project lead) in the case of King's College London acting as a subrecipient. Note, as detailed in [45 CFR 75.361](#) certain situations may require different actions or reference dates. Records relating to unsuccessful applications do not need to be retained.

2. Public access to information

A requirement of this policy is to make the following information publicly accessible, or available within five business days of a request being made: i) the policy itself, which can be found at <https://www.kcl.ac.uk/research/funding/applications>. ii) certain information pertaining to FColS for awards covered by this policy held by Senior/Key personnel. The definition of Senior/Key personnel is defined in section 2 of this policy. The information is only required to be made available for funded awards covered by this policy and prior to expenditure of grant funds, plus updated annually and within 60 days of disclosure of a new SFI. The records should be publicly accessible for 3 years from the most recent update. For compliance, all completed and signed disclosure forms, including Management Plans, where a SFI is identified shall be made accessible for download on this webpage <https://www.kcl.ac.uk/research/funding/applications>. Any written requests should be sent to usresearch@kcl.ac.uk and clearly indicated as a request for this information.

Requests under the Freedom of Information Act shall be handled in accordance with

the King's College London [Freedom of Information Policy](#). Requests should be directed to the [Information Management and Compliance Team](#), and Institutional Designated Officials should liaise with them, providing whatever information is required to fulfil valid requests for information regarding conflicts of interest.

3. Sanctions

In addition to procedures or sanctions with the funder, project lead, or King's College London (as described elsewhere in this policy), as a result of failure to comply with any aspect of this policy, disclosures are also subject to sections 2, 3 and 4 of the [Fraud Act 2006](#). Agreements with any subawardees, subcontractors, external consultants or other third party, who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed, may be terminated for cause. In addition, US Federal regulations may require reports to the US Federal funder of any violations of the US Federal regulations and this King's College London policy.

6. Summary of responsibilities and accountability under this policy

Action/area	Investigator	Department/School/Faculty	Research Grants & Contracts	Other
Compliance with this policy	Responsible and accountable to disclose any FCol as detailed in the policy and agree to and implement any Management Plan as signed and agreed.	Responsible for ensuring that all staff supporting the application to, or award of, funding covered by this policy carries out actions as described in section 4.1 of this policy.	Responsible and accountable to ensure that the policy requirements are actioned; accountable to the funder for implementing the reporting requirements.	Responsible; any subawardee, subcontractor, external consultant or third party where King's College London is the project lead AND the entity is following King's College London policy.
Disclosure of Significant Financial Interests (SFI)	Responsible and accountable; actions are detailed in section 3 of this policy.	Responsible to inform RG&C in cases where they suspect or know that an Investigator has failed to correctly disclose an SFI.	N/A	Responsible and accountable; only if the first conditions above are met.
Training	Responsible and accountable; detailed in section 3 of this policy.	Recommended (optional) for any staff directly supporting or assisting the grant application or award.	Responsible; all RG&G staff implementing this policy should take the training.	Responsible and accountable; only if the first conditions above are met.
Monitoring	Responsible and accountable; Investigators should disclose any SFIs which have not been	Responsible; assisting the Investigator(s) and RG&C (and the 'FCol committee' as appropriate) in complying with this policy and the implementation of any Management Plan.	Responsible; RG&C are responsible for monitoring any subawardees (<i>et al.</i>) who are following this policy	Responsible and accountable; only if the first conditions above are met.

	otherwise reported. Investigators should implement a Management Plan as appropriate.			
Reporting	Responsible; only for ensuring timely completion of actions as detailed in this policy.	Responsible; only for ensuring timely completion of actions as detailed in this policy.	Responsible and accountable; all reporting to the funder is done by RG&C where King's College London is the project lead. RG&C is responsible for passing required details to the project lead in all other cases.	Responsible; only for ensuring timely completion of actions.

Relevant NIH resources:

FAQs relating to FCIs: <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm>

NIH training module: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

Revision history

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