

**University of Surrey Processes regarding
The National Institutes of Health (NIH) Financial Conflict of Interest (FCOI) Policy**

1. Background

- 1.1 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 is at <http://grants.nih.gov/grants/policy/coi/> (the FAQ section is a useful guide through the requirements: http://grants.nih.gov/grants/policy/coi/coi_faqs.htm).
- 1.2 The NIH policy mandates that the University places its policies and procedures for implementing the NIH's requirements on a publicly accessible area of its website and ensures public accessibility of information relating to any FCOI that it has declared under the NIH policy by giving a full written response to each request for such information within five working days.
- 1.3 The policy applies to work funded by the NIH itself and by NIH Institutes (e.g. National Cancer Institute, National Institute of Allergy & Infectious Diseases - see <http://www.nih.gov/icd/>), as well as to other work funded by the Public Health Service of the US Department of Health & Human Services (of which NIH is a part).
- 1.4 The policy relates to everyone who is responsible for the design, conduct, or reporting of research funded by the NIH (Principal Investigators (PIs) and Co-Investigators (Co-Is), as well as any other individuals responsible for the design, conduct, or reporting of the NIH research, including honorary staff, students, technicians, external collaborators, or consultants). All these individuals are referred to in this note and the policy as 'Investigators'. The NIH is clear that it is the role of the individual and the degree of independence with which they work, rather than their title, that is key to whether they fall within the definition of an 'Investigator'.

The policy also applies to any external organisations with which the University collaborates on NIH projects, such as sub-awardees, sub-contractors and external consultants. The University will therefore include applicable terms requiring adherence to the NIH policy in the agreements that it places with these organisations and individuals.

- 1.5 The NIH policy is supplementary to, and should be followed in conjunction with, the University's own policies, procedures and guidelines on related matters, such as Ethical Conduct Procedures: Bribery, Fraud, Gifts, Hospitality and Conflicts of Interest, Code on Good Research Practice, and Code of Practice on Handling Allegations of Research Misconduct.

2. Definition of a Financial Conflict of Interest (FCOI)

- 2.1 In terms of the NIH policy, a financial conflict of interest exists when, after investigation, the University reasonably determines that an Investigator has a **Significant Financial Interest** ('SFI') that is related to an NIH-funded research 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.
- 2.2 A **Significant Financial Interest** 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 University responsibilities (these may include activities such as research, research consultation, teaching, professional practice, University committee memberships, and service on review board panels, etc.):

For any publicly traded Entity¹, a SFI exists if the value of any remuneration (including salary and any payment for services not otherwise identified as salary, e.g. consulting fees, honoraria, paid authorship) received from the Entity in the 12 months preceding the disclosure and the value of any equity interest (including any stock, stock option or other ownership interest as determined through reference to public prices) in the Entity as of the date of disclosure, when aggregated, exceeds US\$ 5,000.

For any non-publicly traded Entity¹, a SFI exists if the value of any remuneration received from the Entity in the 12 months preceding the disclosure, when aggregated, exceeds US\$ 5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest Intellectual property rights and interest (e.g., patents, copyrights) on receipt of income related to such rights and interest.

- 2.3 As SFIs, Investigators must also disclose the existence of any travel related to their University responsibilities that is reimbursed or sponsored by commercial funders. This includes travel paid on behalf of the 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 University's system for claiming expenses and is charged to a research project.

3. Investigators' Responsibilities

3.1 Investigators' main responsibilities under this policy are

- a. **Timely disclosure of Significant Financial Interest within the timelines specified by the NIH**
Failure to disclose in accordance with NIH timelines 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 the annual returns are 'nil' returns.

Initial returns are via completion of the [NIH Pre-Submission Declaration Form](#) and submitted to both their School/Departmental Administrator and RIS Pre-Award. Ongoing and annual returns are via completion of the [Significant Financial Interest Declaration Form](#) to both their School/Departmental Administrator and Finance Post-Award.

- b. **To collect disclosures of Significant Financial Interest of Investigators at other institutions**, where the University has or will subcontract institutions whose staff are to perform part of the project, and forward details to their School/Departmental Administrator to enable reporting to the NIH in accordance with NIH timelines.
- c. **Prompt disclosure of any bias found in the design, conduct or reporting of the project** to the Head of School/Department, Administrator, and Director of Research and Innovation Services.
- d. **Compulsory completion of the NIH online tutorial**
All Investigators must complete the online [NIH FCOI tutorial](#) prior to engaging in research related to any NIH grant and at least every four years. Investigators who are new to the University must complete the training even if they have done so within a four-year period at a previous organisation. There are also additional training requirements depending on circumstances,

¹ In the policy, 'Entity' means any domestic or foreign, public or private organisation (excluding a US Federal/government agency) from which an Investigator (and spouse and dependent children), receives remuneration or in which any person has an ownership or equity interest.

including immediately if the University revises its FCOI policy that affects requirements of Investigators or an Investigator is not in compliance with the policy or management plan. The tutorial must be re-completed every four years.

- 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 the 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 FCOI and adherence to any other requirement of the NIH and University concerning FCOI.
 - g. **Ensuring that any Investigators who are new to the NIH-funded project throughout its duration follow the Investigator guidance and complete the NIH on-line tutorial.**
- 3.2 Non-compliance must be reported to the NIH.

4. School and Departmental Administrators' Responsibilities: Reporting SFIs to NIH

4.1 The University is required to submit to the NIH: initial (no later than at the time of application for research funding), on-going (within 30 days of Investigator discovering or acquiring a new SFI) and annual FCOI reports throughout the full duration of an NIH project. Such reporting and any other reporting relating to FCOI matters is to be coordinated, collected and undertaken by School and Departmental Administrators (collectively referred to in this document as 'Administrators') unless otherwise specified at the time by the NIH.

4.2 Administrators are responsible for collecting all Investigators' initial, on-going and annual SFI declarations and for forwarding details of declared SFIs to their Head of School/Department to determine whether they constitute a 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 there are Investigators in different Schools/Departments involved in the same NIH project, the administrator in the PI's School/Department is responsible for collecting all Investigators' annual SFI declarations for that project and for promptly forwarding details of declared SFIs to the Heads of the PI's and relevant Co-I's School/Department for them to jointly determine any FCOI.

4.3 Where the University has subcontracted to another institution for their Investigators to be involved in a project, the University PI will provide declarations for those Investigators to the Administrators to be included in their reporting to the NIH and for any SFIs to be considered by the Head of School/Department alongside University Investigators' SFIs.

4.4 Where there is a nil return (i.e. returns with no declared SFIs) or where no information on the SFI declaration constitutes a FCOI, the Administrators will ensure the information is submitted to the NIH using the eRA Commons FCOI Module within the 60 day deadline (in case of an Investigator discovering/acquiring a new SFI, within 30 days of such disclosure) or report any FCOI to the lead applicant institution (if the University is not the lead institution) within the deadline set by them.

4.5 All positive returns (i.e. where it is determined that there is a FCOI by the Head of School/Department) will be promptly passed directly from the local administrator to the Director of Research and Innovation Services for review and further action, which will include reporting to the NIH and working with the Investigator and their Head of School or Department to develop and implement management plans to ensure that the FCOI is appropriately dealt with and controlled within the NIH specified timescales; this includes the completion of a formal [Management Plan](#)

which is required to be submitted to the NIH. For clarity, Nil returns are not submitted to a Head of School/Department.

- 4.6 The University are required to submit annual FCOI reports throughout the full duration of a project at the same time that the University are required to submit the annual progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or submission of a NIH prior approval request, whichever is applicable.) The annual FCOI report is not submitted as part of the annual progress report, but separately through the eRA Commons FCOI Module.

The NIH user guide on how SFI/ FCOI reports are to be submitted through eRA Commons is at https://www.era.nih.gov/docs/Commons_UserGuide.pdf.

- 4.7 Administrators are responsible for maintaining all FCOI-related records (including records relating to the reviews of FCOIs) for a project for at least three (3) years from the date a final expenditure report is submitted to the NIH, or such other timescale as specified by the NIH.

5. Head of School/Department's Responsibilities: Determining and managing FCOIs etc.

- 5.1 On receipt of SFI declarations forwarded by Administrators, Head of School/Departments are responsible for determining whether a SFI declaration constitutes a 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 a FCOI has been declared for an Investigator in a different School/Department to the PI's School/Department, the Heads of both School/Department are to jointly determine any FCOI and work on the development of the Management Plan, if appropriate.
- 5.2 Where it is determined that a SFI constitutes a FCOI, the Head of School/Department will instruct the local administrator to pass details to the Director of Research and Innovation Services for review and further action, which will include reporting to the NIH and working with the Investigator and Head of School/Department to develop and implement management plans to ensure that the FCOI is appropriately dealt with and controlled within the NIH specified timescales; this includes the completion of a formal [Management Plan](#) which is required to be submitted to the NIH.
- 5.3 The Head of School/Department will be responsible for monitoring Investigator compliance with Management Plan until completion of the project.
- 5.4 In the event that a bias is identified in the design, conduct or reporting of a project, the Head of School/Department and Director of Research and Innovation Services will promptly notify the NIH, complete a Mitigation Report and take other necessary corrective actions. Examples of conditions or restrictions that might be imposed to manage conflicts of interest may include full public disclosure, appointment of an independent monitor, modification of the research plan, etc.
- 5.4 In the event that an Investigator fails to comply with his/her obligations to the NIH and University with regards to any FCOI, including following an agreed management plan, the Head of School/Department and Director of Research and Innovation Services will promptly notify the NIH and take 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.

- 5.5 The Head of School/Department will inform Administrators on all of the above so that they can ensure the required information is submitted to the NIH within the required timescales.

- 5.6 In the case of non-compliance with NIH and University policies by a University-employed Investigator, the Head of School/Department will take appropriate disciplinary actions, in consultation with the Pro-Vice-Chancellor Executive Dean and Human Resources.

6. Research and Innovation Services (RIS): Pre- and Post- Award Responsibilities

- 6.1 RIS Pre-Award will e-mail all Investigators a [NIH Pre-Submission Declaration Form](#) for Investigators to confirm their completion of the NIH tutorial and disclosure of SFIs, which is required to be signed by all Investigators prior to Head of Pre-Award approving the submission of an application to the NIH.

The email will draw their attention to the responsibilities set out above. This will be undertaken as part of the Pre-Award application process before submission of the application and subsequently reinforced when a successful award / sub-award is received. Completed Declaration Forms will be maintained by Pre-Award in the relevant application/awarded files.

Pre-Award will register Administrators on eRA Commons as required.

- 6.2 RIS Post-Award Programme Management will provide Administrators with the progress report dates for projects to synchronise with SFI reporting.

Administrators will be required to confirm to Programme Management that they have submitted a nil return to NIH. Programme Management will review Investigator SFI disclosures, confirm where needed a FCOI management plan is implemented, and inform Finance Research Post-Award prior to expenditure of funds.

The Programme Manager is responsible for maintaining SFI Declaration Forms and Management Plan for a project for at least three (3) years from the date a final expenditure report is submitted to the NIH, or such other timescale as specified by the NIH.

When setting up a new award/sub-award, the Post-Award stage, the Programme Manager will remind the PI/s that it is their responsibility to ensure that any Investigators who are new to the NIH-funded project throughout its duration are required to follow the Investigator guidance and complete the NIH on-line tutorial.

- 6.3 Where the University is the lead organisation sub-awarding part of the grant to other organisations or individual consultants, RIS Research Contracts will compel subrecipients to comply with grant terms and conditions and all applicable laws in respect of FCOI / SFI obligations in the legal agreement that governs our relationship with them, making their compliance a contractual obligation.

- 6.4 Where an FCOI has been reported, the Director of Research and Innovation Services will review the SFI documentation within sixty (60) days, determine if SFI relates to PHS/NIH-funded research, and take further action if a FCOI exists, which including reporting to the NIH and working with the Investigator and, where applicable, their Head of School or Department to develop and implement a [Management Plan](#) to be submitted to the NIH that ensure that the FCOI is appropriately dealt with and controlled.

If the University identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed during an ongoing PHS/NIH-funded research project, the Director of Research and Innovation Services shall within sixty (60) days review disclosures of SFIs, determine whether the SFI is related to PHS/NIH-funded research; determine whether a FCOI exists;

and if so, implement, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken to manage such FCOI going forward.

Director Research and Innovation Services will lead a [Retrospective Review](#) within 120 days of determination noncompliance when a SFI is not disclosed timely or previously reviewed or whenever a FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose a significant financial interest that is determined to constitute a financial conflict of interest, failure to review or manage such a financial conflict of interest, and failure by the Investigator to comply with the financial conflict of interest management plan.

Director Research and Innovation Services, in coordination with University Governance and Risk Assurance, will provide a full written response to requests for NIH FCOI declared information within five working days.

7. **Forms** are available to staff on publicly accessible webpages and are included in this document as appendices to include
- NIH Pre-Submission Declaration Form
 - Significant Financial Interest Declaration Form
 - Retrospective SFI Declaration Review
 - Management Plan

8. **Non-exhaustive list of NIH reporting timescales**

Report any FCOIs

- prior to expenditure of funds
- within 30 days of an Investigator discovering or acquiring a new SFI
- within 60 days of identification for an Investigator who is newly participating in a project
- within 60 days for new, or newly identified SFIs for existing Investigators
- annually on FCOIs and any changes to management plans
- following a retrospective review to update a previous report, if appropriate
- following a retrospective review within 120 days of the University determining non-compliance for SFIs not disclosed timely or previously reviewed or whenever a FCOI is not identified or managed in a timely manner.

Management plan within sixty days whenever the University identifies a SFI that was not disclosed timely by the Investigator or not previously reviewed by the University.

Appendix 1. University of Surrey NIH Pre-Submission Declaration Form

Declaration by Investigators when submitting applications for funding by US Department of Health & Human Services organisations, such as the National Institutes of Health, the National Cancer Institute and the National Institute of Allergy & Infectious Diseases. This declaration is required for all applications, including those that are routed via other organisations, e.g., universities in the USA.

All investigators applying for funding from any US Department of Health & Human Services organisation must comply with a Financial Conflicts of Interest ('FCOI') Policy by making declarations regarding FCOIs, Significant Financial Interests ('SFIs') and undertaking training before the submission of an application.

In this context, 'Investigators' means anyone who is or would be responsible for the design, conduct, or reporting of the application/project e.g., Principal Investigators (PIs) and Co-Investigators (Co-Is), as well as any other similarly responsible individuals, including honorary staff, students, technicians, external collaborators or consultants. It is the role of the individual and the degree of independence with which that individual works, rather than their title, that determines whether they fall within the definition of an 'Investigator'.

All Investigators must familiarise themselves with the [policy](#) requirements and responsibilities, make the declarations below, and sign and return this form to [RIS Pre-Award](#). Where an application has more than one Investigator, they may make their declarations collectively on one form or on separate forms. R&I Pre-Award will not coordinate approvals for submission until all Investigators have completed a declaration and taken any necessary action. This form may be signed and e-mailed as a pdf.

Information required	Project Details
Title of project	
Funding organisation (e.g., NIH)	
Name of lead organisation	
Details of any external collaborators, including subcontractors, consultants, non-University staff, including University of Surrey staff	

Declaration by Investigator/s

- I/we have read and understood the responsibilities and requirements for Investigators regarding FCOIs and SFIs and agree to abide by them should the application be successful.
- I/we have (each) completed the [NIH FCOI tutorial](#).
- I/we have (each) completed an [SFI disclosure form](#) and submitted it in line with University requirements.

Where completion of the SFI disclosure form has revealed an FCOI, the details are details below. I/we will follow University requirements with regard to any such FCOI.

[Insert FCOI Details]

Declaration made by _____ (Print Name)

Signature _____ Date: _____

Declaration made by _____ (Print Name)

Signature _____ Date: _____

Appendix 2. University of Surry NIH Disclosure of Significant Financial Interest (SFI) Form – Investigators²

Information required	Information / Comments
Name of the Investigator with the SFI	
Investigator's title and role within the NIH-funded project	
Principal Investigator/s on Grant	
NIH grant reference	
Agresso project code	
Name of the entity/ies with which the Investigator has an SFI If none, enter 'N/A'	
Nature of any financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium) For sponsored travel reimbursement, the minimum information to include is: <ul style="list-style-type: none"> • Purpose of the trip • Name of the sponsor/organiser • Destination • Duration If none, enter 'N/A'	
Value of the SFI (dollar ranges are permissible) <ul style="list-style-type: none"> ▪ \$0 - \$4,999; \$5K - \$9,999; \$10K - \$19,999 ▪ Amounts between \$20K and \$100K by increments of \$20K ▪ Amounts above \$100K by increments of \$50K 	

² This form must be retained for at least 3 years after the University has submitted the final statement of expenditure of for the relevant NIH project (or such other timescale as specified by the NIH), as the information it contains will need to be made available within 5 days should the University receive a request to provide such information under the NIH FCOI policy.

<p>If the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value, a statement is required If none, enter 'N/A'</p>	
<p>Other relevant information</p> <p>If none, enter 'N/A'</p>	
<p>Post-review comments by Head of School/Department where the SFI/s <u>are</u> considered to be a Financial Conflict of Interest</p> <p>If the SFI/s constitute an FCOI the form should be sent promptly to the Director of Research and Innovation Services for action, development of a management plan with the Investigator and their Head of School/Department and reporting to NIH</p>	
<p>Post-review comments by either the local administrator <u>only in case of a nil return</u> (i.e. where no SFIs are declared) or by the Head of School/Department where the SFI/s are not considered to be a Financial Conflict of Interest in order to record why the SFI/s were not considered to be a Financial Conflict of Interest linked to the NIH-funded project.</p> <p>If the SFI/s are not considered FCOIs or if there is a nil return, this data should now be reported to NIH via eRA Commons.</p>	
<p>Date of completion</p>	

Appendix 3. University of Surrey NIH Retrospective SFI Disclosure Form³

Information required	Information / Comments
Name of the Investigator with the SFI / FCOI	
Investigator's title and role within the NIH-funded project	
Principal Investigator's Name	
NIH grant reference	
Agresso project code	
Project title	
Name of the entity with which the Investigator has an FCOI	
Reason(s) for the retrospective review	
Detailed methodology used for the retrospective review (e.g. methodology of the review process, composition of the review panel, documents reviewed, etc.)	
Findings of the review	
Impact of any bias found on the project (e.g., extent of harm done, including any qualitative or quantitative data to support any actual or future harm; analysis of whether the research project is salvageable)	
School's/Division's plan of action or actions taken to eliminate or mitigate the effect of any bias found	

³ This form must be retained for at least 3 years after the University has submitted the final statement of expenditure of for the relevant NIH project, as the information it contains will need to be made available within 5 days should the University receive a request to provide such information under the NIH FCOI policy.

Conclusions of the review, including whether the SFI constitutes an FCOI and reasons for the decision, and next steps with regard to reporting to NIH	
Which University individuals have been involved in drawing up this compiling the data on this form (names and roles)	
University Signature (Name and Date of Signature)	
Date of completion	

Appendix 4. University of Surrey NIH FCOI Management Plan⁴

Information required	Information / Comments
Name of the Investigator with the FCOI	
Investigator's title and role on the NIH-funded project	
Principal Investigator/s on Grant	
NIH grant reference	
Agresso project code	
Name of the entity with which the Investigator has an FCOI	
Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)	
<p>Value of the financial interest (dollar ranges are permissible)</p> <ul style="list-style-type: none"> ▪ \$0 - \$4,999; \$5K - \$9,999; \$10K - \$19,999 ▪ Amounts between \$20K and \$100K by increments of \$20K ▪ Amounts above \$100K by increments of \$50K <p>If the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value, a statement is required</p>	
<p>How does the financial interest relate to the NIH-funded project and why has the School/Departmental Designated Official determined that the financial interest conflicts with such research?</p>	

⁴ This form must be retained for at least 3 years after the University has submitted the final statement of expenditure of for the relevant NIH project, as the information it contains will need to be made available within 5 days should the University receive a request to provide such information under the NIH FCOI policy

<p>What are the role and principal duties of the conflicted Investigator in the NIH-funded research project?</p>	
<p>What are the conditions of this management plan?</p>	
<p>Which University individuals have been involved in drawing up this Management Plan (names and roles)?</p>	
<p>How is the management plan designed to safeguard objectivity in the research project?</p>	
<p>How will the management plan be monitored to ensure Investigator compliance?</p>	
<p>Updated Management Plan to any previously submitted to the NIH:</p> <p>What is the status of the management plan (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists)?</p> <p>Include a description of any changes to the management plan since the last FCOI report was submitted to the NIH.</p>	
<p>Other relevant information</p>	
<p>Investigator's signature and Date of Signature (confirmation of the Investigator's understanding of AND agreement to the Management Plan)</p>	
<p>University official (Signature, Name, and Date of Signature)</p>	