



Financial Conflict of Interest (FCOI) Policy for US Public Health Service funded research

POLICY COVERSHEET

Key Details

POLICY TITLE	<i>Financial Conflict of Interest (FCOI) Policy for US Public Health Service funded research</i>
DATE APPROVED	<i>27 June 2023</i>
APPROVING BODY	<i>Research & Innovation Committee</i>
VERSION	<i>2</i>
PREVIOUS REVIEW DATES	<i>July 2020</i>
NEXT REVIEW DATE	<i>June 2026</i>
OUTCOME OF EQUALITY IMPACT ASSESSMENT	<i>No major change</i>
RELATED POLICIES / PROCEDURES / GUIDANCE	<i>Research Integrity & Governance Framework</i>
IMPLEMENTATION DATE	<i>July 2023</i>
POLICY OWNER (JOB TITLE)	<i>REF & Policy Manager</i>
UNIT / SERVICE	<i>RIS</i>
CONTACT EMAIL	<i>kajefferies@cardiffmet.ac.uk</i>

Version Control

VERSION	DATE	REASON FOR CHANGE
<i>1.0</i>	<i>July 2020</i>	<i>First version</i>
<i>1.1</i>	<i>June 2023</i>	<i>Links updated</i>

Policy Hub

For further information on policies:

- 1 You can go to the Secretariat pages on InSite at <https://outlookuwicac.sharepoint.com/sites/Secretariat>;
- 2 You can go to the Policy Hub at cardiffmet.ac.uk/about/policyhub; or
- 3 Contact policies@cardiffmet.ac.uk.

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1 Introduction and Background

- 1.1 Financial Conflict of Interest (FCOI) exists to ensure that research is free from bias resulting from investigator commercial conflicts of interest. This policy establishes standards to promote objectivity and provide a reasonable expectation that the design, conduct and reporting of US Public Health Service (PHS) funded research is not jeopardised by an FCOI. It also ensures adherence with US Federal regulations. The full NIH FCOI policy can be found [here](#).
- 1.2 When applying to or receiving funding from PHS funding bodies, Principal Investigators and their research team must adhere to a number of requirements related to FCOI.
- 1.3 This applies to everyone who applies for, designs a study for or works on a project funded by the NIH. It also applies to all staff applying or working on projects funded by other agencies funded via PHS, a full list of which can be found [here](#).
- 1.4 Cardiff Met is unable to submit grant applications to PHS bodies if applicants are unable to demonstrate that they have undertaken the required training and disclosures. In addition, failure to comply with the policy once a grant has been awarded may incur severe consequences, as identified by the funding body.
- 1.5 The term *investigator* is used throughout this policy to describe all those involved with the project. This includes researchers, administrators, technicians, honorary staff, students, consultants, subcontractors and collaborators.
- 1.6 Compliance with PHS requirements will be managed by Research & Innovation Services (RIS) via the [NIH Significant Financial Interest Declaration Form \(SFI Declaration\)](#) and the [NIH online FCOI training tutorial](#). However, whilst RIS will manage the process, responsibility for adherence to the requirements lies with the Principal Investigator on the project (or institutional lead if the project is operated in collaboration with another institution). As such, the PI must ensure all staff working on the project adhere to this policy by undertaking the requirements set out below. The PI is responsible for the conduct of all investigators working on the project and must ensure all complete the compulsory [NIH online tutorial](#) and the [Cardiff Met SFI Declaration](#) in accordance with required timeframes. This will include any new researchers who begin working on the project at any point.
- 1.7 The responsibilities of each party involved in the compliance process are detailed below.

2 Responsibilities under this policy

2.1 All Investigators

All investigators **MUST** undertake the following responsibilities in order to comply with the FCOI policy:

- a) Complete the compulsory [NIH online tutorial](#) prior to engaging in research related to any NIH grant and at least every four years. Once completed, the investigator **MUST** submit their Certificate of Completion via email to [Orla Govers](#) as evidence that they have satisfied this requirement. In addition, investigators must also undertake the training when:
 - FCOI policy changes affect the requirements of the investigator
 - RIS finds that an Investigator is not compliant with this policy, [the NIH policy on NIH funded projects](#) or any agreed Management Plan.
- b) Disclose any Significant Financial Interest using the [Cardiff Met SFI Declaration Form](#)¹ within the following timeframes:
 - At the time of application for the NIH-funded research
 - At least annually during the period of the award
 - Within 30 days of discovering or acquiring a new SFIFailure to disclose in accordance with these timeframes will result in additional reporting to the NIH.
- c) Adhere to any Management Plan agreed in the case of any identified FCOI. Non-compliance must be reported to the sponsor.
- d) Disclose any bias found in the design, conduct or reporting of the project to the Director of Research.
- e) Adhere to the principles of the [Cardiff Met Research Integrity & Governance Framework](#).

2.2 Associate Dean of Research (ADR)

The ADR must undertake the following responsibilities to comply with the FCOI policy:

- a) Review submitted Cardiff Met SFI Declaration forms, highlight any undeclared financial interests and assess any declared conflicts.
- b) Submit completed forms via email to [Orla Govers](#).

2.3 Director of Research (DoR)

The DoR must undertake the following responsibilities to comply with the FCOI policy:

- a) Act as the institutional official to review disclosures of Significant Financial Interest (SFI)

¹ This will include any SFI related to them personally, their spouse and any dependent children.

- b) Working with RIS, review all submitted Cardiff Met SFI Declaration forms and determine if any declaration of SFI constitutes a financial conflict of interest due to either the impact of the SFI on the project OR the outcomes of the project may have on the SFI.
- c) Working with RIS either,² report any identified FCOI via the NIH's electronic systems within the 60-day deadline OR report any FCOI to the lead applicant within the deadline set by them.
- d) Where relevant, work with the ADR and PI to put in place a Management Plan to manage any potential conflict of interest on the project.
- e) Ensure that the NIH is notified promptly in the event that bias is identified in the design, conduct or reporting of a project and ensure compliance with any relevant internal requirements.
- f) In the event that they become aware of any instance of a newly discovered or acquired SFI, ensure that a Cardiff Met SFI Declaration Form is completed.

2.4 The University (via Research & Innovation Services)

In support of the above requirements, RIS will:

- a) Maintain and enforce an up to date FCOI policy and make the policy available on a publicly accessible website.
- b) Ensure all investigators involved in US PHS funded research applications and awards are aware of this policy and that any updates to the policy are communicated to relevant staff.
- c) Manage the administrative process to identify FCOI and work to manage, reduce or eliminate identified conflicts to the PHS.
- d) Ensure compliance with the policy by:
 - i. ensuring all investigators have completed the [NIH online tutorial](#) according to the required timeframes.
 - ii. issuing reminders to PIs to ensure the Cardiff Met SFI Declaration Form is completed annually by all investigators.
 - iii. ensuring all subcontractors, consultants and collaborators comply with the NIH FCOI policy either through their own FCOI policy or via adoption of the Cardiff Met policy.
 - iv. undertaking annual audits of projects.

² The appropriate reporting mechanism will be detailed in either the contract with the funder or the collaboration agreement with the lead institution.

- e) Submit to NIH initial, ongoing and annual FCOI reports throughout the duration of the project via the [NIH system](#).
- f) Maintain records relating to all investigator disclosures and all actions under this policy for at least three years from the date of final payment.
- g) Report persistent non-compliance internally via the Cardiff Met Research Misconduct Policy, available via the [Policy Hub](#)

3 Related Policies and Procedures

- 3.1 Users of this policy should also refer to the University's Research Integrity and Governance Framework.

4 Review and Approval

- 4.1 This policy will be reviewed by Research & Innovation Committee every three years, in line with the University Schedule for Policy Approval, or more frequently if deemed necessary.

Annexes

Annex 1

NIH Financial Conflict of Interest Declaration: SFI Declaration Form



NIH Financial Conflict of Interest Declaration: SFI Declaration Form

This form must be completed as part of the Cardiff Met Financial Conflict of Interest (FCOI) Policy for US Public Health Service funded research. The full NIH FCOI Policy can be found [here](#).

All members of a research team working on an NIH funded project (known as “Investigators”) are required to complete this form. Please refer to the Cardiff Met Policy for full details of when this form must be completed.

Completed forms should be returned via email to [Orla Govers](#) in R&I Services.

SECTION 1	
To be completed by the Investigator working on the NIH funded project	
Name:	Click here to enter text.
School:	Click here to enter text.
Project Title:	Click here to enter text.
Name of Principal Investigator on project:	Click here to enter text.

Indicate below the reason why you are making this declaration	
I am applying for NIH funding	<input type="checkbox"/>
I have discovered or acquired (eg through purchase, marriage or inheritance) a new Significant Financial Interest (a declaration MUST be made within 10 days)	<input type="checkbox"/>
I am making an annual declaration as required by the NIH	<input type="checkbox"/>

DECLARATION	
Select one of the options below	
A: I do not have any current financial conflict of interests connected to this project	<input type="checkbox"/>
B: I have a potential financial conflict of interest (give full details below)	<input type="checkbox"/>
If you have chosen option B, give full details of the potential financial conflict of interest in the box below	
Click here to enter text.	
By signing this form, I confirm that	
<ul style="list-style-type: none"> I have completed this declaration to the best of my knowledge and have considered all the potential financial conflicts of interest related to me, my spouse and dependent children. I have undertaken NIH online FCOI training within the last four years I have read and understood the Cardiff Met Financial Conflict of Interest (FCOI) Policy for US Public Health Service Funded Research and the Cardiff Met Research Integrity & Governance Framework 	



NIH Financial Conflict of Interest Declaration: SFI Declaration Form

Signed:		Date:	Click here to enter text.
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SECTION 2

To be completed by the relevant Associate Dean of Research within 10 days of the declaration made in Section 1
Please select EITHER A OR B below

A.	The individual named above has confirmed that they have no potential financial conflicts of interest connected to this project and I am satisfied that this is the case.	<input type="checkbox"/>
B.	The individual named above has confirmed that they do have potential financial conflicts of interest connected to this project.	<input type="checkbox"/>

Where B has been selected, please consult with the individual named to provide the following information:

Name of the entity with which the individual has a potential FCOI	Click here to enter text.
Nature of the financial interest (eg equity, consulting fee, travel reimbursement, honorarium) For sponsored travel reimbursement include, as a minimum, details of: <ul style="list-style-type: none"> • the nature of the trip • name of the sponsor / organiser • destination • duration 	Click here to enter text.
Estimated value of the financial support	Click here to enter text.
Any additional information you would like to include	Click here to enter text.

Name:	Click here to enter text.
Signature:	
Date:	Click here to enter text.

SECTION 3

To be completed by the Director of Research within 10 days of the declaration made in Section 1

I have reviewed the information provided in this form and have met with the ADR to review the Significant Financial Interest. As a result I can confirm that (select either A or B below) :

There is no conflict of interest	<input type="checkbox"/>
There is a conflict of interest and I therefore request R&I Services to make an FCOI declaration to the NIH on my behalf (within the 60-day deadline or within 30 days for new disclosures)	<input type="checkbox"/>



Cardiff
Metropolitan
University

Prifysgol
Metropolitan
Caerdydd

Research & Innovation Services

NIH Financial Conflict of Interest Declaration: SFI Declaration Form

Name:			
Signature:		Date:	Click here to enter text.

Please email completed forms to [Orla Govers](#) in R&I Services