



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

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.
- 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](#) 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:

1. 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



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- RIS finds that an Investigator is not compliant with this policy, [the NIH policy on NIH funded projects](#) or any agreed Management Plan.
- 2. 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.
- 3. Adhere to any Management Plan agreed in the case of any identified FCOI. Non-compliance must be reported to the sponsor.
- 4. Disclose any bias found in the design, conduct or reporting of the project to the Director of Research.
- 5. 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:

1. Review submitted Cardiff Met SFI Declaration forms and
 - a. highlight any undeclared financial interests
 - b. assess any declared conflicts
2. 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:

1. Act as the institutional official to review disclosures of Significant Financial Interest (SFI)
2. 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
 - a. the impact of the SFI on the project OR
 - b. the outcomes of the project may have on the SFI
3. Working with RIS either²
 - a. report any identified FCOI via the NIH's electronic systems within the 60-day deadline OR
 - b. report any FCOI to the lead applicant within the deadline set by them.

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

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



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4. 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.
5. 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.
6. 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:

1. Maintain and enforce an up to date FCOI policy and make the policy available on a publicly accessible website.
2. 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.
3. Manage the administrative process to identify FCOI and work to manage, reduce or eliminate identified conflicts to the PHS.
4. Ensure compliance with the policy by:
 - a. ensuring all investigators have completed the [NIH online tutorial](#) according to the required timeframes.
 - b. issuing reminders to PIs to ensure the [Cardiff Met SFI Declaration Form](#) is completed annually by all investigators.
 - c. 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.
 - d. undertaking annual audits of projects.
5. Submit to NIH initial, ongoing and annual FCOI reports throughout the duration of the project via the [NIH system](#).
6. Maintain records relating to all investigator disclosures and all actions under this policy for at least three years from the date of final payment.
7. Report persistent non-compliance internally via the [Cardiff Met Research Misconduct Policy](#).