

UNIVERSITY OF BATH FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY – US PHS RESEARCH FUNDING

INTRODUCTION & PURPOSE

This document is the University of Bath Financial Conflict of Interest (FCOI) policy. It has been developed in order to ensure The University of Bath is compliant with the 2011 updated regulations (42 CFR 50 Subpart F) adopted by US PHS funders (including, but not limited to, NIH, CDC and FDA).

In order to comply with US Public Health Service (US PHS) funding regulations (including the NIH and FDA), staff involved in US Public Health research applications and awards are required to complete [specific training](#) and [documents](#) concerning financial conflicts of interest.

The regulations apply to all investigators funded by, or making an application to, the NIH (or any other US PHS agency) regardless of position or title, who are responsible for the design, conduct or reporting of the research. This includes collaborators and consultants.

This policy aims to ensure research integrity by promoting objectivity in research. This will be done by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from any conflicting financial interest of an investigator.

For more detailed information about the US PHS funder policy, please visit [Promoting Objectivity in Research](#)

It is the responsibility of all Investigators to remain aware of the University of Bath policies and processes on [Conflicts of Interest](#) and to keep their training up to date and reported internally as detailed in this document.

KEY DEFINITIONS

“Financial Conflict of Interest” or “FCOI”

A financial conflict of interest exists when the recipient's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

“Institutional Official”

Deputy Director of Finance.

“Investigators”

Anyone responsible for the design, conduct or reporting of the research, regardless of position or title. This includes collaborators and consultants.

“Monitoring Officer”

Head of Post-Award and Project Management.

“Principal Investigator”

The lead Investigator of the project.

“Significant Financial Interest” or “SFI”

Those financial interests that reasonably appear to be related to the Investigator’s “Institutional responsibilities,” as defined by the Institution. As a result, when read in conjunction with the revised Investigator disclosure requirements under 42 CFR 50.604, the revised Significant Financial Interest definition results in the disclosure by Investigators to Institutions of a wider array of interests on a more frequent basis. In addition to their own, Investigators are required to disclose the Significant Financial Interests of his/her spouse and dependent children.

“The Institution”

This will ordinarily refer to The University of Bath, unless specified otherwise.

Other Key Definitions

TRAINING

Each investigator participating in a research application (either directly or via a sub-contract with another University) or award must complete [on-line training](#) at least every 4 years. Once training is complete, the completion certificate should be sent to the Pre-Award team at pre-award@bath.ac.uk where it will be recorded.

Investigators may be asked to complete this training more frequently if:

- The University revises this policy such that the requirements of Investigators are affected
- The Investigator(s) are new to the University of Bath
- The Investigator(s) are not in compliance with the policy or the management plan

Each investigator must also ensure that their [research integrity](#) training is up to date.

DISCLOSURE, MONITORING AND REVIEW

An [FCOI Disclosure Form](#) must be completed at application and thereafter annually once a grant is awarded, or within 30 days if a Significant Financial Interest (SFI) arises during the award.

Forms completed at application stage should be returned to pre-award@bath.ac.uk.

Forms completed thereafter should be returned to post-award@lists.bath.ac.uk to ensure compliance through the lifetime of the project.

Where a Significant Financial Interest is declared, the Institutional Official responsible for overseeing SFIs will be notified and will review the forms. Only once a decision has been made as a result of this review, may the Institution begin expenditure* on the relevant project (*assuming no FCOIs have been identified that should prevent this). Where an SFI is determined to be an FCOI a management plan, including ongoing monitoring, will be put in place in order to support the work continuing on the project. The management plan must include:

- The role and duties of the conflicted Investigator in the research project
- How the management plan will safeguard objectivity in the research project
- Confirmation of the Investigator's agreement to the management plan

- How the management plan will be monitored to ensure Investigator compliance

If support is required for completing the training or the forms, please seek assistance from:

- [Pre-Award](#) if completing at application stage
- [Post-Award](#) if completing thereafter

RESPONSIBILITIES AND REPORTING

The Principal Investigator and/or Investigators will:

- Ensure all training is completed in line with the requirements of this document in relation to Conflicts of Interest and Research Integrity
- Disclose any SFIs using the [Disclosure Form](#)
- Notify the US PHS funder promptly (ccing the Post-Award team) if bias is found with the design, conduct or reporting of NIH-funded research and submit a Mitigation Report in accordance with regulation [42 CFR 50.605\(a\)\(3\)\(iii\)](#)
- [Adhere to any management plan put in place as a result of FCOI identification](#)
- Report FCOIs to the relevant US PHS funder as required (usually annually) via era Commons

The Pre-Award team will:

- Support and provide guidance on training and form completion at application stage
- Record and escalate all disclosure forms as appropriate

The Post-Award team will:

- Issue FCOI reports to the NIH for the Institution and its subrecipients as required by funder policy
- Record and escalate all disclosure forms as appropriate

The Research Contracts team will:

- Ensure that where a project involves collaborators or consultants, that all partners adhere to the funder regulations on FCOI. The University remains responsible for ensuring partners adhere to the NIH/PHS rules by following their own NIH/PHS FCOI procedure or adopting our procedure where they do not have one.

The Monitoring Officer will:

- Notify NIH promptly if
 - an Investigator fails to comply with the Institution's FCOI policy or
 - an FCOI management plan appears to have biased the design, conduct or reporting of the NIH funded research
- Notify the Institutional Official of either scenario

The Institutional Official will:

- Ensure that, where an SFI is identified to be an FCOI, that an appropriate management plan is put in place within 60 days of disclosure or discovery
- Take corrective action for non-compliance with the FCOI policy or the management plan

- Ensure that, prior to the expenditure of any funds, that any SFI that has been determined as an FCOI is made publicly accessible within 5 days of request

Document Version Control

DOCUMENT TITLE	FINANCIAL CONFLICT OF INTEREST POLICY
AUTHOR	LIZZIE HOPE-DYER, HEAD OF PRE-AWARD
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PROFESSIONAL SERVICES DEPT	RESEARCH & INNOVATION SERVICES
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SPONSOR NAME AND TITLE	JONATHAN KNIGHT, PRO-VC RESEARCH
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REVIEW HISTORY

Version	Amendments	By	Date
1.0	NEW	Lizzie Hope-Dyer	tbc
1.1	Addition of titles for Monitoring Officer and Institutional Official	Lizzie Hope-Dyer (requested by URKEC)	21/05/2021