Financial Conflict of Interest (FCOI) Training Guidance and Disclosure Procedure

Purpose

This document should be read in conjunction with the Financial Conflict of Interest (FCOI) policy. It is intended to support Investigators with their responsibilities and required actions under the policy, in particular around the mandatory training and disclosure processes.

Relevant links

Definitions: https://ecfr.io/Title-42/Section-50.603

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

Disclosure form: https://www.bath.ac.uk/publications/disclosure-form/attachments/disclosure-form.pdf

Process

There are two elements to this process: **Training** and **Disclosure**

Training: Any Investigators (as defined by the policy) participating in a research application or award (either directly or via a sub-contract with another entity) must complete the mandatory training *at least* every four years (this may be more frequent if the University revises this policy, if the Investigator(s) are new to Bath or if the Investigator(s) do not comply with the policy or the management plan).

Once training has been completed, the certificate should be sent to due-diligence@bath.ac.uk where is will be recorded. All disclosures will be recorded in a central register of Significant Financial Interests, linked to both the Investigator and the relevant research project, ensuring a complete audit trail.

Disclosure: The disclosure form must be completed at application stage and annually thereafter once a grant is awarded. Once completed, at any stage, the form should be returned to due-diligence@bath.ac.uk

In addition, Investigators must ensure disclosures are updated within 30 days of acquiring or discovering a new Significant Financial Interest, in line with policy requirements.

The University recognises that externally provided training may not fully meet all accessibility and inclusivity needs. Support, reasonable adjustments, and supplementary guidance will be provided to ensure equitable access for all staff. Please contact due-diligence@bath.ac.uk if you need additional support in order to complete the training.

Review

Where a Significant Financial Interest is declared:

- The Institutional Official will review the disclosure to determine whether a Financial Conflict of Interest exists
- This review must occur **prior to the expenditure of funds**
- Where an FCOI is identified, a formal management plan will be implemented

The review process will be documented and retained for audit purposes.

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
- Identification of any independent oversight mechanisms
- Frequency of monitoring and reporting
- Actions to be taken in the event of non-compliance

Examples of management strategies may include (but are not limited to):

- Independent review of research data
- Disclosure of FCOI in publications and presentations
- Modification of the Investigator's role on the project
- Appointment of an independent monitor
- Reduction or elimination of the financial interest

Non-Compliance and Retrospective Review

Where disclosures are not submitted on time or are incomplete:

- The matter will be escalated to the Monitoring Officer
- A retrospective review may be initiated in line with the FCOI Policy

Simple Process Diagram

1. Training completed → Recorded centrally
2. Disclosure submitted → Logged in register
3. Review by Institutional Official
4. FCOI?
    - No → proceed
    - Yes → management plan
5. Report to PHS
6. Annual updates + monitoring
7. Non-compliance → retrospective review