Financial Conflict of Interest (FCOI) Policy

Contents

1.0 Purpose and Scope

1.1 This policy sets out the University of Bath's approach to identifying, disclosing, reviewing, managing and reporting Financial Conflicts of Interest (FCOI) in relation to research funded by the United States Public Health Service (PHS), including the NIH, CDC, and FDA.

1.2 The purpose is to ensure compliance with PHS regulations (42 CFR Part 50 Subpart F) and promote objectivity in research.

1.3 This policy applies to all staff and individuals involved in PHS-funded research, including investigators, collaborators, consultants and subrecipients.

2.0 Definitions

2.1 *Financial Conflict of Interest (FCOI):* A situation in which the University determines that an Investigator's Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research

2.2 *Investigator:* Any individual responsible for the design, conduct, or reporting of research, regardless of role or title. This includes collaborators and consultants. If you are not sure if this applies to you, please reach out to due-diligence@bath.ac.uk to check.

2.3 *Significant Financial Interest (SFI):* A financial interest (of the Investigator or their immediate family) that reasonably appears to relate to institutional responsibilities, including:

- Remuneration and/or equity interests exceeding $5,000 in a publicly traded entity
- Any equity in a non-publicly traded entity
- Intellectual property rights and income
- Reimbursed or sponsored travel (with specified exclusions)
- Exclusions include salary from the University, and income from public or not-for-profit entities.

2.4 *Institutional Official:* The Director of Finance Operations (or delegated nominee) responsible for determining whether an FCOI exists

2.5 *Monitoring Officer:* The Due Diligence and Compliance Manager responsible for oversight and escalation of compliance issues.

2.6 Other related definitions can be found here https://ecfr.io/Title-42/Section-50.603

3.0 Roles and Responsibilities

Role	Responsibility
Investigators	Complete required training (including ensuring research integrity training is up to date) Disclose Significant Financial Interests in a timely manner Comply with any management plans
Principal Investigator	Ensure all project team members comply with this policy
Institutional Official	Review disclosures and determine whether FCOIs exist Ensure appropriate management plans are implemented Act in cases of non-compliance
Monitoring Officer	Oversee compliance with this policy Provide guidance at application stage Collect and record disclosures Submit required reports to PHS funders Escalate issues and notify funders where required
Research Contracts	Ensure appropriate FCOI provisions in subrecipient agreements

4.0 Policy

Training

All Investigators must complete FCOI training prior to engaging in PHS-funded research and at least every four years thereafter. Completion of training is a condition of participation in PHS-funded research.

Please see the associated guidance document for the link that will take you to the training.

Disclosure

Investigators must disclose all Significant Financial Interests

- At application stage
- Annually during the award
- Within 30 days of acquiring a new interest

Please see the associated guidance document for the link that will take you to the disclosure form.

Review and Management

The University will review all disclosures and determine whether an FCOI exists. Where an FCOI is identified, it must be managed through an appropriate management plan prior to the expenditure of funds.

No expenditure of PHS funding may occur until identified FCOIs have been reviewed, managed and, where required, reported.

Reporting

The University will report FCOIs to PHS funders:

- Prior to expenditure
- Within 60 days of identifying new FCOIs
- Annually thereafter

Public Accessibility

Information on FCOIs will be made publicly available via a web-based system *or* within five working days of a written request, in accordance with PHS requirements.

Subrecipients

The University will ensure that all subrecipient agreements:

- Clearly establish whether the subrecipient will follow its own FCOI policy or the University's policy
- Require subrecipients to certify that their FCOI policy is compliant with PHS regulations
- Require subrecipients to report identified FCOIs to the University within defined timeframes (no later than **30 days** after identification)

Where the subrecipient adopts the University's policy, the subrecipient Investigators must comply with all disclosure and training requirements specified herein.

Monitoring and Non-Compliance

Compliance with this policy will be monitored through disclosure processes and oversight by the Monitoring Officer. Failure to comply may result in:

- Suspension of research activity or funding
- Reporting to the PHS funder
- Implementation of corrective actions

Retrospective Review and Mitigation

Where a Significant Financial Interest (SFI) is not disclosed in a timely manner, not previously reviewed, or where non-compliance with a management plan is identified, the University will:

- Conduct a retrospective review of the Investigator's activities and the PHS-funded research project within **120 days** of the determination of non-compliance
- Document the review
- Promptly notify the PHS funder and submit a mitigation report in accordance with the regulatory requirements

Record Retention

The University will retain all records relating to Financial Conflicts of Interest, including:

- Investigator disclosures
- Review determinations
- Management plans
- Training records

Records will be retained for a period of at least three years from the date of submission of the final expenditure report to the PHS funder, or longer where required by other regulations or institutional policy.

5.0 Related Policies and Procedures

University of Bath Conflict of Interest Policy
Code of good practice in research integrity
FCOI Training Guidance and Disclosure Procedure (separate document)

6.0 Document Information

Owner	Pro-Vice Chancellor Research
Author	Head of Research Funding, RIS
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