

Investigator Financial Conflict of Interest (FCOI) Policy

Valid to:	31 March 2026
Executive Owner:	Louise Bracken
Business Owner:	Andrew Poole
Endorsed by:	Research and Knowledge Exchange Committee
Approval Authority:	Board of Governors

1. Introduction

- 1.1 When applying to and receiving funding from the American Public Health Service (PHS), including National Institutes of Health (NIH), all Investigators and research teams are obligated to demonstrate compliance with the NIH Financial Conflicts of Interest (FCOI) Regulation¹. The purpose of this regulation ([42 CFR 50.601](#)) is to “promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from Investigator Financial Conflicts of Interest (FCOI).”
- 1.2 The policy will be subject to review by Research and Knowledge Exchange Committee. This will be carried out at least every three years, or when updates are required.

2. Purpose of the Investigator FCOI Policy

- 2.1 The purpose of this policy is to comply specifically with the 2011 requirements (adopted by NIH grants and cooperative agreements) defined in the Objectivity in Research Regulations [42 CFR Part 50 Subpart F](#) and [45 CFR Part 94 \(contracts\)](#).
- 2.2 It is recognised that effective interactions between research institutions, government, the private sector, and industry are essential, however, the resulting relationships are increasingly complex, and may involve financial interests that give rise to an FCOI through its potential to directly and significantly impact the design, conduct or reporting of an Investigator’s research in return for a financial benefit to the Investigator or his/her immediate family.
- 2.3 An FCOI may arise even though no improper conduct or unethical behaviour has occurred. Northumbria and its Investigators are responsible for identifying and managing these FCOIs to strengthen accountability and transparency, promote research objectivity, and maintain the integrity of research findings.
- 2.4 The policy is intended to be used only where an Investigator (as defined in section 9) is applying for or has been awarded funding from the American PHS and the Investigator is involved in or responsible for the design, conduct, or reporting of said funded research.

3. Northumbria Responsibilities

- 3.1 Northumbria is responsible for ensuring adherence to Regulation [42 CFR 50.604](#). Specifically, to:
- 3.1.1 Assign the role of a Designated Official or Officials to review a Significant Financial Interest (SFI) disclosure and make a determination of FCOI.
 - 3.1.2 Promote objectivity in research.
 - 3.1.3 Manage, in accordance with [Subpart F - Promoting Objectivity in Research](#), the initial and ongoing reporting requirements to the PHS.
 - 3.1.4 Where an FCOI is identified, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI.

¹ The FCOI regulation is applicable to all NIH awards except Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) applications and awards.

- 3.1.5 Conduct a Retrospective Review within 120 days of determining noncompliance and submit a Mitigation Report via the eRA Commons FCOI Module.
- 3.1.6 Require each PHS-supported Investigator to complete the [NIH FCOI training](#).
- 3.1.7 Make this policy publicly accessible.

4. Training for all Investigators

- 4.1 All Investigators who are subject to the Investigator Conflict of Interest Policy are mandated to complete the [NIH FCOI training](#) prior to engaging in research for or on behalf of Northumbria, and at least every four years thereafter or immediately if (1) an Investigator is new to Northumbria; (2) Northumbria's Investigator Conflict of Interest Policy changes in a manner affecting Investigator requirements; or (3) Northumbria finds that an Investigator is non-compliant with the Investigator Conflict of Interest Policy or an applicable management plan.
- 4.2 Subrecipient Investigators who are subject to Northumbria's Investigator Conflict of Interest Policy and participate in PHS-funded research are also required to complete the [NIH FCOI training](#).
- 4.3 On completion of training, all Investigators are required to send a certificate of completion to the Research Delivery team in Research and Innovation Services (RIS).

5. Disclosure requirements

- 5.1 Investigators are required to disclose their foreign and domestic Significant Financial Interests (SFIs), (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities that meet or exceed the regulatory definition of SFI.
- 5.2 Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure.
- 5.3 Each of the following SFIs should be disclosed on the SFI Declaration Form, where the aggregated value of remuneration received in the 12 months preceding the disclosure exceeds \$5,000 (circa £4,100 as at March 2023):
 - 5.3.1 With regard to any **publicly traded entity**, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - 5.3.2 With regard to any **non-publicly traded entity**, an SFI exists when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - 5.3.3 Financial interests received in connection **with patents, copyrights, know-how or other intellectual property rights** (e.g., royalties, license fees, equity, or other consideration), including consideration received pursuant to an agreement to share royalties related to such intellectual property rights.
 - 5.3.4 Any **advisory relationship, consulting, outside teaching, or scientific/academic appointment**, both paid and voluntary, as well as any unpaid appointment that provides the Investigator with access to, or in-kind support for, laboratory space, research materials, supplies, equipment, staff participation or living expenses.
 - 5.3.5 Occurrence of any foreign or domestic **reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the Investigator's institutional responsibilities. The disclosure requirement also applies to the Investigator's spouse and dependent children.
 - 5.3.6 **Disclosure is not required** for the following: (1) salary or other remuneration paid by the Northumbria to the Investigator, if the Investigator is currently employed or otherwise appointed by the Northumbria; (2) royalties, fees or other consideration paid to the Investigator by Northumbria for the intellectual property owned by Northumbria

(i.e. not personally owned by the Investigator); (3) sponsored or reimbursed travel stemming from a U.S. federal, state, or local government agency, a U.S. institution of higher education as defined in 20 U.S.C. 1001(a), a U.S. academic teaching hospital, a U.S. medical centre, or a U.S. research institute that is affiliated with a U.S. institution of higher education.

5.4 An SFI is only deemed related to PHS/NIH-funded research when Northumbria, through its Designated Official, reasonably determines that the SFI: could be affected by the PHS/NIH-funded research; or is in an entity whose financial interest could be affected by the research.

5.5 An FCOI exists when Northumbria, through its Designated Official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.

5.6 Investigators are required to promptly disclose SFIs to accurately reflect their external activities as follows: (1) no later than at the time of application for PHS-funded research; (1) within 30 days of acquiring and/or discovering a new SFI, including through purchase, marriage, or inheritance; (3) within 30 days of a material change to a previously disclosed SFI; (4) at least annually during the period of an award

6. Review and monitoring requirements

6.1 Northumbria's Designated Official shall, within 60 (sixty) calendar days, review disclosures of SFIs, determine whether the SFI is related to PHS/NIH-funded research; determine whether an FCOI exists; and, if so, implement, on at least an interim basis, a robust Management Plan that shall specify the actions that have been, and will be, taken to manage such FCOI.

6.2 Where a Management Plan is required, the Designated Official and Head of Research Delivery and Compliance will monitor Investigator compliance with said plan until completion of the project.

6.3 Northumbria's Research Delivery and Compliance function will continually monitor the FCOI and Investigator compliance with the FCOI Management Plan and where necessary may require and develop a project specific monitoring process.

6.4 Non-compliance with the Investigator Conflict of Interest Policy or Management Plan may be considered a disciplinary matter, a determination will be made by the Designated Official and relevant senior authorities in Northumbria and as detailed within Northumbria's disciplinary procedures.

7. Reporting requirements

7.1 Northumbria will send initial, annual and revised FCOI reports, including all required information defined in the regulation and/or NIH's [FAQ H.5](#), to the NIH via the eRA Commons FCOI Module for both Northumbria and its subrecipients, if applicable.

7.2 Reporting shall be submitted within 60 (sixty) calendardays of identification for a new investigator and where a newly identified FCOI is identified for existing investigators.

7.3 Where new information is discovered following the completion of a Retrospective Review, and where appropriate, Northumbria shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

7.4 Northumbria shall notify NIH if: bias is found with the design, conduct or reporting of PHS/NIH-funded research and include the requirement to submit a Mitigation Report to explain what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation and if an Investigator fails to comply with Northumbria's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research.

8. Maintenance and retention of records

8.1 Northumbria will maintain all FCOI-related records relating to Investigator disclosures of financial interests, including the review of, and response, to such disclosures (whether or not a disclosure resulted in the determination of an FCOI) and all relevant actions for at least 3 years from the date the final expenditures report is submitted to the PHS (NIH) or, where applicable, from the dates specified under regulation [45 CFR 75.361](#).

8.2 Records relating to conflict-of-interest matters covered under this Investigator Conflict of Interest Policy for PHS-funded research must be maintained for a minimum period of three years after any applicable research project's final financial report is submitted to the funding agency, or until three years after the final action has been taken on any audit, litigation, or claim, whichever is longer. Records for conflict-of-interest matters relating to other funded research will be maintained in accordance with Northumbria's [Record Retention Schedule](#).

9. Definitions

Code of Federal Regulations (CFR) – is published annually and is the codification of the general and permanent rules published in the Federal Register by the departments and agencies of the Federal Government of the United States. It is divided into 50 titles that represent broad areas subject to Federal regulation.

Designated Official – Individual(s) assigned as responsible for reviewing SFI disclosures, making FCOI determinations and developing and implementing plans to manage said FCOIs.

Financial Conflict of Interest (FCOI) - means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Institutional Responsibilities - mean an Investigator's professional activities on behalf of Northumbria including, but not limited to, research, research consultation, teaching, professional practice, institutional committee memberships and service on panels such as institutional review boards.

Investigator - refers to the Principal Investigator (PI) and any other person regardless of title or position who is responsible for the design, conduct or reporting of research funded by the PHS, which may include Co-Is (internal or external), collaborators and consultants. This list is not exhaustive.

Management Plan – where a financial conflict of interest exists, a Management Plan must be implemented and will include: (1) the role and principal duties of the conflicted Investigator in the research project; (2) conditions of the management plan; (3) how the management plan is designed to safeguard objectivity in the research project; (4) confirmation of the Investigator's agreement to the management plan; (5) how the management plan will be monitored to ensure Investigator compliance; and (6) other information as needed.

PHS - means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH)

Significant Financial Interest (SFI) - means a financial interest of the Investigator and the Investigator's spouse or domestic partner and dependent children, alone or in combination, that reasonably appears to be related to the Investigator's institutional responsibilities. Types of financial interests can include remuneration, equity interests in a publicly and non-publicly traded entity, intellectual property rights and interests, and reimbursed or sponsored travel.

10. Roles and Responsibilities

Role	Responsibility
Secretary to Board and Head of Governance	Act as the Designated Official as described in the policy.
Head of Research Delivery and Compliance	Ensuring the implementation and maintenance of robust processes are in place in the Research

	Delivery team to ensure PHS-funded grants are compliant with this policy.
Investigator (as defined above)	Adherence to this policy.

11. Applicable to

The policy applies to any staff involved in or responsible for the design, conduct, or reporting of research funded by the NIH, including (but not limited to):

- Principal Investigators (PIs)
- Co-Investigators (Co-Is)
- Honorary Staff
- Post-Doctoral Researchers
- Students, Technicians
- External collaborators or consultant

12. Related Policies, Procedures and Other Resources

The NIH FCOI Policy is supplementary to, and should be followed in conjunction with, Northumbria's own policies, procedures, and guidelines on related matters, including but not limited to:

- [Anti-Money Laundering Policy](#)
- [Gifts and Hospitality Policy](#) and [Guidance on the giving and receiving of gifts and hospitality](#)
- [Fraud and Bribery Policy](#)
- [Disclosure and Conflicts of Interests Policy](#)
- [Disclosure and Conflicts of Interests Policy: Related Parties and Related Party Guidance](#)
- [Financial Regulations](#)
- [Ethics and Integrity Guidance, Policies and Procedures](#)
- [NIH Financial Conflict of Interest Policy](#)
- [NIH Online Tutorial](#)
- [NIH FCOI FAQs](#)
- [Key Definitions - Subpart F - Promoting Objectivity in Research](#)
- Reimbursed or sponsored travel - [Frequently Asked Questions E.1](#)

13. Version

Version no.	Reviewer	Date	Changes
1.1		13.03.23	
1.2	Andrew Poole	14.03.23	Minor additions
1.3	Richard Elliott	15.03.23	Governance detail