



# THE UNIVERSITY *of* EDINBURGH

## Public Health Service of the United States Department of Health and Human Services

### University of Edinburgh Financial Conflict of Interest Policy (“FCOI Policy”)

**Note:- this Policy and the associated Procedure apply primarily to recipients of funding from awarding components of the Public Health Service of the United States.**

#### 1. Policy Statement and Purpose

The United States Public Health Service (PHS) has adopted regulations 42 CFR Part 50 and 45 CFR Part 94 on Promoting Objectivity in Research (available at [http://grants.nih.gov/grants/policy/coi/fcoi\\_final\\_rule.pdf](http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)). These regulations describe the actions that the individual and the institution must take in order to promote objectivity in research.

The regulations apply to all grants, cooperative agreements and research contracts funded by the PHS (but not to Phase I Small Business Innovation Research or Small Business Technology Transfer program grants).

The basic requirement of the regulations is that Investigators applying for PHS funding (which includes funding from PHS Awarding Components like the National Institutes of Health and the U.S. Food and Drug Administration) must disclose to their institution any Significant Financial Interests related to their institutional responsibilities and undertake ongoing training on the regulations and their institution’s Financial Conflict of Interest policy.

Institutions that receive PHS funding, including the University of Edinburgh, are required to maintain processes for ensuring compliance with the regulations. These include processes for reviewing the Significant Financial Interests of their Investigators, identifying those Interests that could directly and significantly affect the design, conduct or reporting of PHS-funded research, and managing those conflicting interests in line with the regulations.

This Policy and the accompanying Procedure (the “FCOI Procedure”) set out the individual and institutional responsibilities to be fulfilled, as well as the processes to be followed, in order to comply with the regulations.

**Note:-** the requirements and responsibilities set out in this Policy and Procedure exist **in addition** to those described in the University’s Policy on Conflict of Interest (available at

## 2. Definitions

**Designated Official** means the individual within the University who is responsible for the solicitation and review of disclosures of Significant Financial Interests related to the Investigator's Institutional Responsibilities.

**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.

**FCOI Regulation** means Title 42 of the U.S. Code of Federal Regulation, Part 50, Subchapter F and Title 45 of the U.S. Code of Federal Regulation, Part 94, on Promoting Objectivity in Research.

**Institutional Responsibilities** means an Investigator's professional activities on behalf of the institution (e.g., teaching, administration, research, or clinical care). Specifically, these include:-

- Externally sponsored research or scholarly activities (includes activities such as proposing, conducting, and analysing research and disseminating results);
- Departmental/University research (includes participation in study sections, peer review of manuscripts, or effort on non-sponsored research);
- Instruction/University Supported Academic activities (including preparation for and presentations of formal and informal courses to students/trainee groups, mentoring students and trainees, and participation in resident training);
- Clinical service activities;
- Administrative activities including serving as Head of Department, Programme Director, or service on institutional committees, participation in department activities or faculty advisory boards, etc.; or
- Special Service activities on behalf of the University including institutional community service.

Institutional responsibilities do not include:-

- Volunteer individual community or public service unrelated to one's responsibilities on behalf of the University; or
- Other activities over and above or separate from responsibilities in the primary position.

**Investigator** means the Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants. The Principal Investigator or Project Director, upon consideration of the individual's role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

**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).

**PHS Awarding Component** means the organisational unit of the PHS that funds the research that is subject to the FCOI Regulation. Examples of PHS Awarding Components that may fund research carried out at the University include the National Institutes of Health (NIH), the Foundation for the National Institutes of Health, the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration.

**Significant Financial Interest (“SFI”)** means:-

**A. A financial interest** consisting of one or more of the following interests of the Investigator (**and those of the Investigator's spouse/civil partner and dependent children**) that reasonably appears to be related to the Investigator's Institutional Responsibilities:-

- (i) **With regard to any publicly traded entity, a Significant Financial Interest** exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds US \$5,000. For purposes of this definition, 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;
- (ii) **With regard to any non-publicly traded entity, a Significant Financial Interest** exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds US \$5,000, or when the Investigator (or the Investigator's spouse/civil partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).

**Note:-** Salary, royalties, or other remuneration paid by the University to the Investigator **are not classed as Significant Financial Interests**, if the Investigator is currently employed or otherwise appointed by the University;

- (iii) **Intellectual property rights and interests** (e.g., patents, copyrights), upon receipt of income exceeding US \$5,000 related to such rights and interests.

**Note:-** Income related to intellectual property rights assigned to the University and agreements to share in royalties related to such rights **are not classed as Significant Financial Interests**, if the Investigator is currently employed or otherwise appointed by the University .

**B. Any reimbursed or sponsored travel** (i.e. that which is reimbursed to or paid on behalf of the Investigator, the Investigator's spouse/civil partner or dependent children) exceeding US \$5,000 **related to the Investigator's Institutional Responsibilities**. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a United States federal, state, or local government agency, a United States Institution of Higher Education as defined at 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of Higher Education. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organiser, the destination, and the duration.

This provision does not apply to travel which an Investigator books through the University's designated travel provider or claims through the University's expenses system.

**C.** The term Significant Financial Interest does not include the following types of financial interests:-

- (i) salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
- (ii) any ownership interest in an institution held by the Investigator, if the institution is a commercial or for-profit organization;
- (iii) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;

- (iv) income from seminars, lectures, or teaching engagements sponsored by a United States Federal, state, or local government agency, a United States Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education; or
- (v) income from service on advisory committees or review panels for a United States Federal, state, or local government agency, a United States Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

**Senior/Key Personnel** means the Project Director or Principal Investigator, and any other person identified as senior/key personnel by the University in the grant application, progress report, or any other report submitted to the PHS Awarding Component by the University under the FCOI Regulation. Senior/Key Personnel are encompassed within the definition of Investigator.

**Subrecipient Institution** means a consortium member, or an institution to which the University has subcontracted, or will subcontract, elements of a project and whose staff are to perform part of the project.

### 3. Disclosure of Significant Financial Interests

Investigators' principal responsibilities under the FCOI Policy and Procedure are:-

- 3.1 Timely disclosure to the University's Designated Official of SFIs within the timelines specified by the PHS agencies.
- 3.2 Timely collection of disclosures of SFIs of Investigators at Subrecipient Institutions and forwarding these to the University's Designated Official.
- 3.3 Prompt disclosure to the University's Designated Official of any bias found in the design, conduct or reporting of the project.
- 3.4 Compulsory completion of ongoing training requirements.
- 3.5 In the case of projects involving clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment that has been designed, conducted, or reported by an

Investigator, to make public disclosure of FCOIs that have not been appropriately managed or reported at each public presentation of the results of relevant projects (and as addenda to previously published presentations).

- 3.6 Co-operation with the Designated Official and other colleagues in local University units in the development and implementation of management plans, and the conduct of the retrospective reviews, for the management of any identified FCOI. Compliance with any other funder or University requirements in connection with the management of FCOIs. Adherence to any such management plan(s) agreed with the University.
- 3.7 Co-operation with the Designated Official and other colleagues in local University units in the provision to the PHS Awarding Component of all information required in relation to Investigator disclosures of financial interests and the University's review of, or response to, such disclosures, whether or not determined to constitute a FCOI.
- 3.8 Project Directors/Principal Investigators are responsible for ensuring and co-ordinating compliance by Investigators on the PHS-funded research project, including those at Subrecipient Institutions, with the Investigator responsibilities set out under the FCOI Policy and Procedure.

Non-compliance with this Policy and Procedure, or with a funder's requirements, by a University employed Investigator may constitute misconduct and could result in disciplinary action. In serious cases this could result in dismissal.

For further information on responsibilities, processes and timescales relating to the disclosure of SFIs, please refer to the FCOI Procedure and to the guidance available on the University's Financial Conflict of Interest Hub (see here:- [Financial Conflict of Interest Compliance \(sharepoint.com\)](#))

#### **4. Review of disclosed Significant Financial Interests, determination and management of Financial Conflicts of Interest**

The University shall, in a timely manner, review all disclosures of Significant Financial Interests by Investigators, determine which Interests constitute Financial Conflicts of Interest and implement a plan to manage any Financial Conflict of Interest, so that the objectivity of the research is protected.

In circumstances where any Financial Conflict of Interest is not identified or managed in a timely manner, then in addition to implementing a management plan in respect of that Financial Conflict of Interest, the University shall, in a

timely manner, conduct a retrospective review to check whether there has been bias in the design, conduct or reporting of the research.

In the event that the retrospective review identifies bias, the University shall promptly notify the PHS Awarding Component, complete a mitigation report and take such as other corrective actions as are required.

For further information on responsibilities, processes and timescales relating to the review of disclosed SFIs and the determination and management of FCOIs, please refer to the FCOI Procedure and to the guidance available on the University's Financial Conflict of Interest Hub (see here:- [Financial Conflict of Interest Compliance \(sharepoint.com\)](#))

## **5. Reporting of Financial Conflicts of Interest to the PHS Awarding Component**

The University shall, in a timely manner, report to the PHS Awarding Component, all Investigator Significant Financial Interests that are determined to constitute Financial Conflicts of Interest.

Following initial reporting of any Financial Conflict of Interest, the University shall report to the PHS Awarding Component on an annual basis for the duration of the PHS-funded research project, addressing the ongoing status of the Financial Conflict of Interest and any changes to the related management plan.

In circumstances where a Financial Conflict of Interest is not identified or managed in a timely manner and a retrospective review is conducted, the University shall, in a timely manner, update its report to the PHS Awarding Component in respect of that Financial Conflict of Interest.

Where the failure of an Investigator to comply with the FCOI Policy or Procedure, or with a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the University shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

For further information on responsibilities, processes and timescales relating to the reporting of FCOIs, please refer to the FCOI Procedure and to the guidance available on the University's Financial Conflict of Interest Hub (see here:- [Financial Conflict of Interest Compliance \(sharepoint.com\)](#))

## 6. Subrecipient Institutions

If the University carries out PHS-funded research through a Subrecipient Institution, the University as the awardee institution must take reasonable steps to ensure that any Investigators at Subrecipient Institutions comply with the FCOI Regulation.

For further information on responsibilities, processes and timescales relating to working with Subrecipient Institutions, please refer to the FCOI Procedure and to the guidance available on the University's Financial Conflict of Interest Hub (see here:- [Financial Conflict of Interest Compliance \(sharepoint.com\)](#))

## 7. Public Accessibility and Record Keeping

7.1 Before the University's expenditure of any funds under a PHS-funded research project, the University shall ensure public accessibility of information concerning any SFI disclosed to the University that meets the three criteria set out at sections 7.1.1, 7.1.2 and 7.1.3 below. The information shall be made available either via the University website, or by written response to any requestor within five business days of a request:-

7.1.1 The SFI was disclosed and is still held by the Senior/Key Personnel;

7.1.2 The University determines that the SFI is related to the PHS-funded research; and

7.1.3 The University determines that the SFI is a FCOI.

7.2 Where the University uses its website for the purposes of section 7.1, the information that the University posts will be updated at least annually and, in addition:-

7.2.1 **within 60 days** of the University's receipt, or identification, of information concerning any additional FCOI of the Senior/Key Personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a FCOI of Senior/Key Personnel new to the PHS-funded research project; and

7.2.2 shall remain available on the webpage for **at least 3 years** from the date that the information was most recently updated.

The webpage used to host the information posted in line with section 7.1 shall note that the information provided is current as of the date of



publication and is subject to updates on **at least an annual basis** and **within 60 days** of the University's identification of a new FCOI.

7.3 Where the University responds to written requests for the purposes of section 7.1, the University will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on **at least an annual basis** and **within 60 days** of the University's identification of a new FCOI, which can be requested subsequently by the requestor.

7.4 The University shall maintain records relating to:-

7.4.1 all Investigator disclosures of SFIs, and the University's review of, and response to, such disclosures (whether or not a disclosure resulted in the University's determination of a FCOI); and

7.4.2 all actions under the University's FCOI Policy and Procedure or, where relevant retrospective review

for a period of **at least 3 years** from the date the final expenditures report is submitted to the PHS Awarding Component or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

7.5 The University shall ensure that the University's up-to-date FCOI Policy and Procedure are publicly accessible on the University website.

For further information on Public Accessibility and Record keeping, please refer to the FCOI Procedure and to the guidance available on the University's Financial Conflict of Interest Hub (see here:- [Financial Conflict of Interest Compliance \(sharepoint.com\)](#))

## 8. Related policies, procedures and guidance

[University of Edinburgh Policy on Conflict of Interest](#)

## 9. Policy History and Review

<b>Formal Approval Date:</b>	10 October 2023
<b>Final Approving Authority:</b>	University Executive
<b>Effective Date:</b>	18 October 2023
<b>Scheduled Review Date:</b>	October 2026

## 10. Version Control and Minor Amendments:

<b>Current Version Number:</b>	Version 1.0
<b>Date of minor amendments:</b>	N/A
<b>Nature of change:</b>	N/A
<b>Approved by Policy Sponsor/ Approving Authority:</b>	N/A
<b>Effective date:</b>	18 October 2023

## 11. Alternative Format

If you require this document in an alternative format, please contact:

Alan Campbell, Research Integrity Manager, Edinburgh Research Office  
Email: [alan.campbell@ed.ac.uk](mailto:alan.campbell@ed.ac.uk)

Room 2.15, Charles Stewart House  
9-16 Chambers Street  
Edinburgh  
EH1 1HT