



THE UNIVERSITY *of* EDINBURGH

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

University of Edinburgh Financial Conflict of Interest Procedure (“FCOI Procedure”)

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

1. Purpose and Scope

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). 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 Procedure and the accompanying Policy (the “FCOI Policy”) 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 (FCOI Policy Sections 3.1 – 3.8)

- 3.1 Investigators must make the following disclosures of SFIs to the University's Designated Official:-
 - 3.1.1 Initial disclosures, using the appropriate form, no later than the **time of application**;
 - 3.1.2 Ongoing disclosures, using the appropriate form, **within 30 days** of acquiring or discovering a new SFI; and
 - 3.1.3 Annual returns (even if these are 'nil' returns), using the appropriate form, throughout the life of the project.

- 3.2 Project Directors/Principal Investigators must collect the following SFIs from Investigators at Subrecipient Institutions and forward them to the Designated Official:-
- 3.2.1 Initial disclosures, using appropriate form, no later than the **time of application**;
 - 3.2.2 Ongoing disclosures, using the appropriate form, **within 30 days** of acquiring or discovering a new SFI; and
 - 3.2.3 Annual returns (even if these are 'nil' returns), using the appropriate form, throughout the life of the project.
- 3.3 Investigators must promptly disclose to the University's Designated Official any bias found in the design, conduct or reporting of the project.
- 3.4 Investigators are required to complete, on an ongoing basis, all necessary University and funder training requirements. In the case of projects funded by the National Institutes of Health ("NIH"), this includes:-
- 3.4.1 Completing the University training and NIH Financial Conflict of Interest online Training Module (<https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>) prior to engaging in research related to any NIH-funded grant, and at least every four years during the life of the project. Investigators must also complete the University training immediately in the event that the University revises the FCOI Policy or Procedure in any way that affects the requirements of Investigators.
 - 3.4.2 In the case of Investigators who are new to the University, new to a Subrecipient Institution, or who join a project at any point after its commencement, completing the University training and NIH Financial Conflict of Interest online Training Module immediately following the start of their employment or the date they joined the project. Investigators who are new to the University, or to a Subrecipient Institution, must complete the NIH Financial Conflict of Interest online Training Module even if they have already done so within the previous four years at a previous organisation.
 - 3.4.3 In situations where the University finds that an Investigator is not in compliance with the FCOI Policy or Procedure, or with a management plan developed in accordance with section 4 below, completing the University training and NIH Financial Conflict of Interest online Training Module immediately.

- 3.5 Where projects involve 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, any FCOIs that have not been appropriately managed or reported must be publicly disclosed at each public presentation of the results of relevant projects (and also published as addenda to previously published presentations).
- 3.6 Investigators are required to co-operate 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. Investigators are required to comply with any other funder or University requirements in connection with the management of FCOIs. Investigators are required adhere to any such management plan(s) agreed with the University.
- 3.7 Investigators are required to co-operate 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 and processes relating to the disclosure of SFIs, please refer to the FCOI Policy 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 (FCOI Policy Section 4)

- 4.1 Before the University's expenditure of any funds under a PHS-funded research project, the Designated Official shall:-

- 4.1.1 Review all Investigator disclosures of SFIs;
 - 4.1.2 Determine whether any SFIs relate to PHS-funded research; and
 - 4.1.3 Determine whether a FCOI exists and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI. Management plans shall be developed in liaison with colleagues in local University units.
 - 4.1.4 Complete the FCOI reporting and management steps set out at section 5.1 below.
- 4.2 In situations where, during the course of an ongoing PHS-funded project:-
- (i) An Investigator who is new to participating in the research project discloses a SFI; or
 - (ii) An existing Investigator discloses a new SFI to the University;
- The Designated Official shall, **within 60 days**:-
- 4.2.1 Review the disclosure of the SFI;
 - 4.2.2 Determine whether it is related to PHS-funded research;
 - 4.2.3 Determine whether a FCOI exists and, if so, 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 financial conflict of interest. Depending on the nature of the SFI, the University may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Designated Official's review. Management plans shall be implemented in liaison with colleagues in local University units.
 - 4.2.4 Complete the FCOI reporting and management steps set out at sections 5.2.1 and 5.2.2 below.
- 4.3 In situations where the University identifies a SFI that was not disclosed in a timely manner by an Investigator or which, for whatever reason, was not previously reviewed by the University during an ongoing PHS-funded research project (for example, was not reviewed

in a timely manner, or reported by a Subrecipient Institution), the Designated Official shall, **within 60 days**:-

- 4.3.1 Review the SFI;
 - 4.3.2 Determine whether it is related to PHS-funded research;
 - 4.3.3 Determine whether a FCOI exists and, if so, 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 financial conflict of interest going forward. Management plans shall be implemented in liaison with colleagues in local University units.
 - 4.3.4 Complete the FCOI reporting and management steps set out at sections 5.2.1 and 5.2.2 below.
- 4.4 In situations where a FCOI is not identified or managed in a timely manner, including:-
- (i) Failure by the Investigator to disclose a SFI that is determined by the University to constitute a FCOI;
 - (ii) Failure by the University to review or manage such a FCOI; or
 - (iii) Failure by the Investigator to comply with a FCOI management plan,

Within 120 days of the University's determination of non-compliance, the Designated Official shall complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or any portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. The retrospective review shall be conducted in liaison with colleagues in local University units. The University shall document the retrospective review.

- 4.4.1 Based on the results of the retrospective review, if appropriate, the University shall update the FCOI report that was previously submitted in terms of section 5, specifying the actions that will be taken to manage the FCOI going forward.
- 4.4.2 If bias is found, the University is required to notify the PHS Awarding Component promptly and submit a mitigation report to that PHS Awarding Component.

- 4.4.3 Following submission of the mitigation report, the University will submit FCOI reports annually, as described in section 5.

Depending on the nature of the FCOI, the University may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the FCOI or the Investigator's non-compliance is determined and the completion of the University's retrospective review.

- 4.4.4 In the case of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment, corrective actions will include Investigators being required to disclose FCOIs in public presentations of the results of the project (and as addenda to previously published presentations).

For further information on responsibilities and processes relating to the review of disclosed SFIs and the determination and management of FCOIs, please refer to the FCOI Policy 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

Initial and ongoing FCOI reporting and failure by an Investigator to comply with the FCOI Policy or Procedure, or FCOI management plan (FCOI Policy Section 5)

- 5.1 Before the University's expenditure of any funds under a PHS-funded research project, the University shall:-
 - 5.1.1 Provide to the PHS Awarding Component a FCOI report regarding any Investigator's SFI found by the University to constitute a FCOI; and
 - 5.1.2 Ensure that the University has implemented a management plan in accordance with section 4 above in respect of such FCOI.

In cases where the University identifies a FCOI and eliminates it prior to the expenditure of PHS-awarded funds, the University is not required to submit a FCOI report to the PHS Awarding Component.

- 5.2 In the case of SFIs found to constitute FCOIs subsequent to the University's initial FCOI report during the course of an ongoing PHS-funded research project, such as where a SFI is disclosed by an Investigator who is new to the research project, or where an existing Investigator discloses a newly acquired SFI, the University shall, **within 60 days:-**
- 5.2.1 Provide to the PHS Awarding Component a FCOI report regarding the FCOI;
 - 5.2.2 Ensure that the University has implemented a management plan in accordance with section 4 above in respect of such FCOI;
 - 5.2.3 Where such FCOI report involves a SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed or managed by the University, for example because it was not reviewed or reported in a timely manner by a Subrecipient Institution, the University also is required to complete a retrospective review in line with section 4.4 and, where appropriate, to update the FCOI report with the findings; and
 - 5.2.4 In the event that a retrospective review completed in line with section 4.4 identifies bias, the University will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
- 5.3 In relation to any FCOI previously reported in line with sections 5.1 and 5.2 in connection with an ongoing PHS-funded research project, the University shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project.
- 5.4 In the event that 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 and processes relating to the reporting of FCOIs, please refer to the FCOI Policy 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

Ensuring compliance with the FCOI Regulation by Investigators at Subrecipient Institutions (FCOI Policy Section 6)

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.

Steps to be taken to ensure that Investigators at Subrecipient Institutions comply with the FCOI Regulation include:-

- 6.1 Incorporating as part of a written agreement with the Subrecipient Institution terms that establish whether the FCOI Policy of the University, or that of the Subrecipient Institution will apply to the Subrecipient Institution's Investigators.
 - 6.1.1 If the Subrecipient Institution's Investigators must comply with the Subrecipient Institution's FCOI Policy, the Subrecipient Institution shall certify as part of such agreement that its FCOI Policy complies with the FCOI Regulation. If the Subrecipient Institution cannot provide such certification, the agreement shall state that the Subrecipient Institution's Investigators are subject to the FCOI Policy of the University as the awardee institution for disclosing SFIs that are directly related to the Subrecipient Institution's work for the University as awardee institution;
 - 6.1.2 If the Subrecipient Institution's Investigators must comply with the Subrecipient Institution's FCOI Policy, the agreement shall specify time period(s) for the Subrecipient Institution to report all identified FCOIs to the University as awardee institution. Such time period(s) shall be sufficient to enable the University to provide timely FCOI reports, as necessary, to the relevant PHS Awarding Component, as required by the FCOI Regulation;
 - 6.1.3 If the Subrecipient Institution's Investigators must comply with the University's FCOI Policy, the agreement shall specify time period(s) for the Subrecipient Institution to submit all Investigator disclosures of SFIs to the University, as awardee institution. Such time period(s) shall be sufficient to enable the awardee institution to comply in a timely manner with its review, management, and reporting obligations under the FCOI Regulation.

- 6.2 Providing FCOI reports to the relevant PHS Awarding Component regarding all FCOIs of all Subrecipient Institution Investigators in line with the FCOI Regulation, i.e., prior to the expenditure of funds and **within 60 days** of any subsequently identified FCOI.

For further information on responsibilities and processes relating to working with Subrecipient Institutions, please refer to the FCOI Policy 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

Senior/Key Personnel FCOI data (FCOI Policy Section 7)

- 7.1 The information that the University makes publicly available for the Purposes of section 7.1 of the FCOI Policy shall be as follows:-
- 7.1.1 The name of the Senior/Key Personnel;
 - 7.1.2 The title of the Senior/Key Personnel and their role within the research project;
 - 7.1.3 The name of the entity in which the SFI is held;
 - 7.1.4 The nature of the SFI (for example, equity interest, consulting fees, travel reimbursement, honoraria etc.); and
 - 7.1.5 The approximate US dollar value of the SFI (US dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or, alternatively, a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
- 7.2 Where the University uses its website for the purposes of section 7.1 of the FCOI Policy, the information that the University posts will be updated:-
- 7.2.1 **at least annually**; and
 - 7.2.2 **within 60 days** of the University's receipt or identification of information concerning any additional SFI of the Senior/Key Personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a SFI of Senior/Key

Personnel who are new to the PHS-funded research project, where such SFIs meet the criteria set out at sections 7.1.1, 7.1.2 and 7.1.3 of the FCOI Policy.

The relevant page on the University website shall note that the information provided is current as of the date listed 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 of the FCOI Policy, 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 Information that is subject to the public accessibility requirement set out at section 7.1 of the FCOI Policy must remain available for responses to written requests, or accessible on the University's website for **at least three years** from the date that the information was most recently updated.

For further information on Public Accessibility and Record keeping, please refer to the FCOI Policy 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

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

10. Version Control and Minor Amendments:

Current Version Number:	Version 1.0
Date of minor amendments:	N/A
Nature of change:	N/A
Approved by Policy Sponsor/ Approving Authority:	N/A
Effective date:	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

Room 2.15, Charles Stewart House

9-16 Chambers Street

Edinburgh

EH1 1HT