



University of  
South Australia

# PHS/NIH Project Financial Conflict of Interest (FCOI) Guidelines

Guidelines issued under the University of South Australia's Research Integrity Policy

These guidelines are issued under the University of South Australia's [Research Integrity Policy](#) (Policy Number AB-66) to support compliance with the United States Public Health Services/National Institutes of Health (PHS/NIH) requirements when applying for, accepting and conducting research using PHS/NIH funding. These guidelines ONLY apply to PHS/NIH funding opportunities and funding awards.

The NIH requires review of, and compliance with [Code of Federal Regulations](#), 'Subpart F – Promoting Objectivity in Research (**Regulation**)' (available at [eCFR :: 42 CFR Part 50 Subpart F -- Promoting Objectivity in Research](#)). Guidance in respect of the Regulation is available on the NIH website:

[Financial Conflict of Interest | grants.nih.gov](#)

[Frequently Asked Questions \(FAQs\) | grants.nih.gov](#)

[FCOI Training | grants.nih.gov](#)

Acknowledging with thanks the University of Melbourne for providing its consent to use the University of Melbourne's 'PHS/NIH Project Financial Conflict of Interest (FCOI) Requirements' document as a basis for this guideline.

Unless defined in this document or within the University of South Australia's policy framework, or unless the contrary intention appears, capitalised words and phrases used in these guidelines that are not otherwise defined will have the meaning given in the Regulation or NIH guidance.

## 1. Purpose

PHS/NIH seeks to promote objectivity in research through its FCOI policy to ensure that the design, conduct and reporting of PHS/NIH-funded research will be free from bias resulting from Investigator financial conflicts of interest.

The Regulation requires that the University of South Australia (**University**) facilitate financial disclosures of Investigator significant financial interests make a determination of FCOI, develop a management plan identifies, discloses and manages FCOI where it reasonably determines that:

- (a) an Investigator has a 'Significant Financial Interest' (**SFI**) related to an PHS/NIH-funded research project; and
- (b) that SFI could affect the objectivity of the design, conduct, or reporting of PHS/NIH-funded research.

To make this determination, Investigators must declare their SFI to the University prior to NIH/PHS-funded research commencing and throughout that research.

In addition, the PHS/NIH requires:

- regular and compulsory PHS/NIH FCOI training for all Investigators;

- management of identified FCOI;
- enforcement mechanisms and remedies for non-compliance;
- the publication of some FCOI information; and
- the maintenance of records.

These requirements may differ from, and are in addition to, the University's general requirements including those relating to conflicts of interest under the University's [Management of Conflict of Interest Policy](#) (Policy number C-36). These requirements must be addressed by Investigators for any PHS/NIH proposal or project.

The disclosure requirements relate to all significant sources of funding, including those relating to other University activities of an Investigator.

## 2. Application

The requirements of these guidelines apply to any individual who meets the definition of "Investigator" (see section 3.1 below).

The University's first named Investigator for a PHS/NIH project (**Principal Investigator**) has additional responsibilities.

## 3. Key concepts

### 3.1 Designated Official

Dean of Research/Director of Institute/senior executive as relevant to the Investigator under the University's Conflicts of Interest Policy.

### 3.2 Financial Conflict of Interest

A Financial Conflict of Interest (**FCOI**) is a SFI that could directly and significantly affect the design, conduct or reporting of PHS-funded research.

### 3.3 Investigator

An Investigator is the project director or principal investigator for a PHS/NIH-funded project, 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 collaborators and consultants. An Investigator may be an employee, officer or contractor of a Subrecipient.

### 3.4 Significant Financial Interest

A Significant Financial Interest (**SFI**) is a financial interest consisting of one or more of the following interests of an Investigator (or those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities.

- (a) 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 USD \$5,000. For the purposes of this definition:
  - (i) remuneration includes, but is not limited to, salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); and
  - (ii) 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.

- (b) Regarding 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 USD \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest in the entity (e.g., stock, stock option, or other ownership interest).
- (c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income in excess of USD \$5,000 related to such rights and interests.
- (d) For the purposes of making a Disclosure, Investigators also must disclose the occurrence of any reimbursed or sponsored travel exceeding USD \$5,000 (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 their Institutional Responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a US federal, state or local government agency, a US institution of higher education, or an academic teaching hospital, medical centre or research institute that is affiliated with a US institution of higher education. This Disclosure will include, at a minimum: the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration.

The term 'SFI' does not include the following types of financial interests:

- (a) 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;
- (b) 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;
- (c) income from seminars, lectures, or teaching engagements sponsored by a US federal, state, or local government agency, a US institution of higher education or an academic teaching hospital, medical centre or research institute that is affiliated with a US institution of higher education; or
- (d) income from service on advisory committees or review panels for a US federal, state or local government agency, a US institution of higher education or an academic teaching hospital, medical centre or research institute that is affiliated with a US institution of higher education.

### 3.5 Subrecipient

A Subrecipient includes a subcontractor or consortium member in respect of PHS/NIH-funded research undertaken by the University.

## 4. Responsibilities

### 4.1 For the purposes of these Guidelines:

- (a) **'Investigator'** means the Principal Investigator and any other person the University determines is responsible for the design, conduct or reporting of the research.
- (b) **'Principal Investigator'** is the University's first named investigator on the PHS/NIH grant.

### 4.2 Investigators

Investigators are required to:

- (a) undertake FCOI training prior to commencing any PHS/NIH-funded research at the University and at least every four years. This training will include informing Investigators about the FCOI policy, aspects regarding the Investigator's responsibilities regarding disclosure of SFI in accordance with

these guidelines and the Regulation. Training on the Regulation is available through the [NIH FCOI Online Tutorial](#) (see section below on training requirements);

- (b) assist the University's Principal Investigator to complete any FCOI screening processes at the pre-award stage;
  - (c) disclose any and all SFIs (and those of the Investigator's spouse/common law partner and dependent children) that reasonably appear to be related to the Investigator's Institutional responsibilities (e.g. research, research consultation, teaching, etc.) using the University's conflict of interest disclosure processes and submit to the relevant Designated Official, with a copy provided to the UniSA Research Office (Research Projects Management team) as follows:
    - (i) at the time of application (refer See NIH's FAQ D.3. at [Frequently Asked Questions \(FAQs\) | grants.nih.gov](#))
    - (ii) annually as prescribed by the Institution;
    - (iii) within 30 days of acquiring or discovering a new SFI arising during the course of an PHS/NIH project; or
    - (iv) in regard to new Investigators to a PHS/NIH project, within 30 days of that Investigator joining the project;
  - (d) assist with the development of an appropriate management plan for any identified SFI determined by the University to be related to the NIH/PHS-funded research (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the PHS/NIH-funded research) and that could directly and significantly affect the design, conduct or reporting of the PHS/NIH project;
  - (e) comply with these guidelines and with any management plan developed to manage any identified FCOI;
  - (f) assist with completing any reports that are required to be provided to the PHS/NIH by the University; and
  - (g) review in its entirety and comply with all other obligations under the Regulation.
- (a) and must comply with all Investigator Responsibilities and in addition:

#### 4.3 UniSA Research Office, Post-award (Research Projects Management)

The UniSA Research Office must:

- (a) confirm that the information disclosed in the FCOI screening form is still current and, if not, require that the Investigator to update the form; and
- (b) ensure that all University Investigators involved in PHS/NIH projects are aware of, comply with and make any disclosures required under these guidelines, including completing the FCOI disclosure form for any significant financial interests identified in the FCOI Screening Form.

#### 4.4 Designated Officials

Designated Officials must:

- (a) review disclosures of Significant Financial Interests and determine if a FCOI exists (refer to 'Determination of FCOI' below);
- (b) manage FCOI, including through the development and implementation of management plans and monitoring compliance (refer to 'Management Plans'), with Institutional oversight/escalation to UniSA Research Office;

- (c) maintain local-level records relating to all Investigator disclosures of financial interests and review of, and actions taken related to, such disclosures for at least three years from the date of submitting the final expenditures report to NIH, or, where applicable, from other dates specified in Title 45 Code of Federal Regulation 75.361 for different situations;
- (d) report FCOI of any Investigator to the PHS Awarding Components; and
- (e) comply with any other obligations of a 'designated official' under the Regulation.

#### 4.5 Institutional responsibilities

The University must:

- (a) maintain an up-to date, written, enforced policy of FCOI which complies with the Regulation, and publish the policy on the University website (ie these guidelines);
- (b) inform each Investigator of the University's policy on FCOI, the Investigator's responsibilities regarding disclosure of SFI and of the Regulation;
- (c) require each Investigator to complete training as required by the Regulation;
- (d) if PHS-funded research is undertaken through a Subrecipient, take reasonable steps to ensure the compliance of the Subrecipient with the Regulation by taking the steps specified in the Regulation;
- (e) appoint Designated Officials;
- (f) require Investigators to disclose SFI in accordance with the Regulation;
- (g) provide guidelines consistent with the Regulation for Designated Officials to determine whether an Investigator's SFI is a FCOI;
- (h) take actions as necessary to manage FCOI, including FCOI of Subrecipient's Investigators;
- (i) report FCOI to the relevant PHS Awarding Component in accordance with the Regulation;
- (j) maintain records relating to all Investigators disclosures of financial interests and the University's review of, and response to, these disclosures;
- (k) establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance with the Regulation; and
- (l) provide certification in each application for PHS/NIH funding of the matters described in this guideline as specified in the Regulation.

## 5. Disclosure requirement

### 5.1 Who must disclose SFI?

Each Investigator (including each Investigator employed or contracted by a Subrecipient) must disclose any SFI.

### 5.2 What must be disclosed?

All SFI must be disclosed to the relevant Designated Official. The initial disclosure must include all SFI of the Investigator in the 12 months preceding the disclosure or as of the date of disclosure as noted in the SFI definition.

### 5.3 **When must disclosure occur?**

#### (a) **Initial disclosure**

Initial disclosure must be made at or before the time of application for PHS-funded research.

#### (b) **Ongoing disclosure**

Further disclosure must be made:

- (i) within 30 days of discovering or acquiring a new SFI (including but not limited to a purchase, marriage, inheritance, etc.); and
- (ii) on an annual basis, during the term of the PHS-funded research, disclosure of:
  - (A) all SFI received in the 12 months preceding the disclosure that were not previously reported; and
  - (B) updated information regarding any previously disclosed SFI.

#### (c) **New to the University:**

All Investigators who are new to the University and are applying for or receiving PHS funding, or who are participating in a PHS-funded research project, must make the initial disclosure within 20 days of joining the project, and the ongoing disclosures as noted above.

## 6. **Training Requirements**

6.1 Each Investigator must understand their responsibilities under these guidelines (including the responsibilities regarding disclosure of SFI) and the Regulation and must complete the NIH on-line tutorial: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> (further guidance regarding NIH training is available at <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>).

6.2 The training must be completed:

- (a) prior to engaging in PHS/NIH-funded research;
- (b) at least once every four years; and
- (c) immediately when any of the following circumstances apply:
  - (i) the University revises these guidelines in any manner that affects the requirements of Investigators;
  - (ii) by any Investigator who is new to the University; or
  - (iii) an Investigator is not in compliance with these guidelines or a management plan.

6.3 When the NIH on-line tutorial has been completed, the Investigator must save an electronic copy of the certificate generated through the system and provide a copy to UniSA Research Office (Research Projects Management team).

## 7. **Determination of FCOI**

7.1 The relevant Designated Official for an Investigator must determine, on behalf of the University, whether an FCOI exists for the purposes of the Regulation unless other arrangements are prescribed in the University's Conflicts of Interest Policy in which case those requirements will apply.

7.2 The Designated Official must determine reasonably whether the SFI declared by the Investigator:

- (a) could be affected by the PHS/NIH research; or
- (b) is in an entity whose financial interest could be affected by the PHS/NIH research.

- 7.3 If the SFI is determined by the Designated Official to be related to the PHS/NIH research, the Designated Official must determine whether the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH research.
- 7.4 If the Significant Financial Interest is determined by the Designated Official to both:
- (a) relate to the NIH research; and
  - (b) affect the design, conduct or reporting of the PHS/NIH research, it is an FCOI, and must be managed through a management plan (see section 8 below).
- 7.5 The Designated Official may involve the Investigator in the determination of whether a significant financial interest is related to the PHS/NIH research, but the determination of whether an FCOI exists must be made solely by the Designated Official.
- 7.6 Designated Officials can seek advice from People Talent and Culture (Conflicts of Interest) or the UniSA Research Office.

## **8. Management plans**

- 8.1 Where a FCOI is identified, the Designated Official must develop and implement a management plan within 60 days of the FCOI being identified that specifies the actions that have been, and will be, taken to manage such financial conflict of interest.
- 8.2 Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
- (a) public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
  - (b) restrictions on staff members working on the project;
  - (c) conditions or restrictions advised by the Institution's Institutional Review Board(s), Human Research Ethics Committee, Institutional Animal Care and Use Committee, Animal Ethics Committee, Institutional Biosafety Committee, and the reviewing committee(s) (if approved under a mutual acceptance model), and any other regulatory, ethics, compliance, or safety committee as may be applicable to the conduct of the research project;
  - (d) for research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
  - (e) appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
  - (f) modification of the research plan;
  - (g) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - (h) reduction or elimination of the financial interest (e.g., sale of an equity interest); or
  - (i) severance of relationships that create financial conflicts.
- 8.3 The Designated Official must appropriately monitor compliance with any management plan until the completion of the PHS/NIH project.

## **9. Non-compliance and remedies**

- 9.1 Where an FCOI has not been promptly identified or managed including an Investigator has failed to disclose a SFI, the Institution has failed to review a SFI, or the Investigator has failed to comply with a

management plan, the Institution must conduct a retrospective review of the Investigator's activities and the PHS-funded research project to determine if the PHS-funded research was biased in its design, conduct or reporting.

- 9.2 If an incidence of non-compliance or suspected non-compliance with the Regulation or a management plan is identified, Investigators and Designated Officials must immediately:
- (a) report the non-compliance or suspected non-compliance to the UniSA Research Office; and
  - (b) take all necessary steps to retrospectively comply with the Regulation or management plan relating to disclosure, determination, and management of SFI.
- 9.3 The UniSA Research Office will, within 120 days of identifying a non-compliance, undertake a retrospective review of the Investigator's activities and the PHS/NIH project under its research integrity processes in order to determine whether any PHS/NIH research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct or reporting of such research. Investigators must fully and promptly cooperate with any review.
- 9.4 If bias is found, a mitigation report will be submitted to the NIH in accordance with the Regulation and NIH's FAQ I.3. at [Frequently Asked Questions \(FAQs\) | grants.nih.gov](https://www.grants.nih.gov/frequently-asked-questions).
- 9.5 Where non-compliance relates to PHS/NIH research investigating the safety or effectiveness of a drug, medical device or treatment, the University will require the Investigators to disclose the FCOI in each public presentation of the results of the research and request an addendum to previously published presentations, and the Investigators must comply with this and any other requirement of the University.
- 9.6 Non-compliance with these guidelines, including failure to disclose SFI or failure to comply with any management plan, may constitute research misconduct.
- 9.7 In the event of non-compliance with any requirements under these guidelines, the University may take corrective actions in accordance with applicable University policies and procedures, including withholding access to NIH funds or suspending project activity.
- 9.8 Corrective action taken, or to be taken, by the University to address the failure of an Investigator to comply with these guidelines or a FCOI management plan which appears to have biased the design, conduct or reporting of PHS-funded research will be notified by the University to the PHS Awarding component.

## **10. Record-keeping**

- 10.1 Principal Investigators, Investigators and Designated Officials must create, maintain, and store all local-level records relating to implementation of these guidelines for at least three years following the submission of the final report to the NIH (or such other period as required under the Regulation), and in accordance with the University's record-keeping policies or legislated records retention requirements.
- 10.2 In addition, the University will store and retain all relevant central records in accordance with NIH and University requirements. Records of disclosed SFI, Investigator determinations, management plans, reviews and any resulting action and any other documentation required by these guidelines will be maintained by the University for at least three years from the date of submission of the final expenditures report for NIH research or, where applicable, from other dates specified in 45 C.F.R. 75.361 (see FAQ A.11).

## **11. Public accessibility requirements**

- 11.1 University will maintain an up-to-date, written, enforced policy (and associated procedures) on financial conflicts of interest, that complies with the Regulation and make such policy available via the University's website.



- 11.2 The University will, within 5 business days of a request, disclose requisite details of any FCOI whenever such information is requested. Requests should be made to [RISDirector@unisa.edu.au](mailto:RISDirector@unisa.edu.au).
- 11.3 After an award has been granted, but prior to the University's expenditure of any funds under a PHS-funded research project, the University will make available, via a publicly accessible website the information listed in clause 11.4 concerning any SFI that meets the following criteria:
- (a) SFI was disclosed and is still held by an Investigator who has been identified by the University as senior/key personnel for the NIH-funded research project in the grant application, progress report, or any other report submitted to the NIH;
  - (b) the University determines that the SFI is related to the NIH-funded research; and
  - (c) the University determines that the SFI is a FCOI.
- 11.4 The University must post on the publicly accessible website or make available in response to written requests the following minimum information:
- (a) the Investigator's name;
  - (b) the Investigator's title and role with respect to the research project;
  - (c) the name of the entity in which the SFI is held;
  - (d) nature of the SFI;
  - (e) approximate dollar value of the SFI within the ranges of:
    - (i) USD \$0 – USD \$4,999;
    - (ii) USD \$5,000 – USD \$9,999;
    - (iii) USD \$10,000 – USD \$19,999;
    - (i) amounts between USD \$20,000 – UD \$100,000 by increments of USD \$20,000;
    - (ii) amounts above USD \$100,000 by increments of USD \$50,000 or
    - (iii) a statement that a value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
  - (f) the entity with which the Investigator has a FCOI, to enhance transparency and accountability.
- 11.5 The University will update the information listed in paragraph 11.4 annually and within 60 days of changes to the information.
- 11.6 The information listed in paragraph 11.4 will remain available for responses to written requests or for posting via the University's publicly accessible website for at least 3 years from the date that the information was most recently updated.

## **12. Requirements regarding Subrecipients**

- 12.1 If the University is the primary awardee for PHS/NIH funding, then the research collaboration agreement with any Subrecipient will provide for the compliance of any Investigator employed or contracted by the Subrecipient with 42 CFR 50.604.
- 12.2 These contractual obligations will require the sub-awardee to ensure compliance of its Investigators with the Regulation, including:
- (a) disclosure of all SFI to the University's Designated Official:
    - (i) prior to the expenditure of funds; and

- (ii) within the time period specified in the subcontract to enable the Designated Officer to develop and implement a management plan within 60 days of any FCOI being identified;
- (b) compliance with management plans;
- (c) consent to the publication of details of FCOI as required by the Regulation;
- (d) notification of any non-declared SFI or non-compliance with any management plan to the University; and
- (e) declaration that all SFI have been identified and disclosed and any management plan has been managed in accordance with NIH requirements.