



Public Health Service/National Institute of Health Awards Financial Conflict of Interest (FCOI) Procedure

This Guidance is issued under the Research Grants and Contracts operational level procedures to support compliance with PHS/NIH requirements when applying for accepting and conducting research using PHS/NIH funding. The full NIH Financial Conflict of Interest (FCOI) policy and associated detailed guidance (including FAQs) are available on the NIH website:

- [NIH FCOI Policy](#)
- [NIH FCOI FAQs](#)

1. Purpose

Public Health Services/National Institutes of Health (**PHS/NIH**) promotes objectivity in research through its FCOI policy and requirements by establishing standards that provide expectations that the design, conduct, and reporting of PHS/NIH funded research will be free from bias resulting from any Investigator financial conflicts of interest. The NIH FCOI policy requires that the University identifies, discloses and manages the FCOI of grant recipients where it is reasonably determined that an Investigator has a 'Significant Financial Interest' (SFI), related to a PHS/NIH-funded research project, that could affect the objectivity of PHS/NIH-funded research.

To make this determination, Investigators must declare their SFI to the University.

Additionally, the PHS/NIH requires regular and compulsory PHS/NIH FCOI training for all Investigators and continuous disclosure and management of identified FCOIs.

These requirements are in addition to, the University's general requirements relating to conflicts of interest, and as such must be addressed by investigators on any PHS/NIH proposal/project. The **disclosure requirements relate to all significant sources of funding, including those relating to investigators' other University activities.**

2. Application

The requirements for **Investigators** set out in this Guidance apply to any person identified as senior or key personnel in a PHS/NIH grant application or progress reports who can directly or materially influence the research, or who is responsible for the design, conduct, and reporting of such research, whether the University is a Prime Awardee or a Sub-awardee.

The University's first named Investigator (**Principal Investigator**) has additional responsibilities. Investigators' Heads of School or Dean act as the University's **Delegated Authority** to determine whether a FCOI exists and implement and monitor management plans.

3. Responsibilities

3.1 Investigators

- (a) Prior to commencing any PHS/NIH funded research at the University, Investigators must undertake the [NIH FCOI training](#).
- (b) Assist the University's Principal Investigator to complete the University's FCOI Screening Declaration at the pre-award stage;
- (c) Disclose any and all identified 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 using the [confidential disclosure statement](#) submitted to Head of School/Dean, with a copy to Research Grants and Contracts (RGC) Director at the post-award stage:
 - prior to expending PHS/NIH funding;
 - annually post-award;
 - within 30 days of any new SFIs arising during the course of an PHS/NIH project; and
 - within 30 days of new investigators joining the project;
- (d) Assist with the development of a management plan for any identified SFIs determined by the University to directly and significantly affect the design, conduct or reporting of the PHS/NIH project (FCOI);
- (e) Comply with this Guidance and with any management plan developed to manage any identified FCOIs;
- (f) Assist with completing any reports that are required to be provided to the PHS/NIH by the University; and
- (g) Comply with any other obligations under the NIH policy.

3.2 Principal Investigator

- (a) The Principal Investigator is the University's first named investigator on the PHS/NIH grant.
- (b) The Principal Investigator must comply with all Investigator Responsibilities and in addition:

Pre-award

- complete a FCOI screening declaration with respect to all University Investigators and submit the FCOI Screening Declaration to RGC Compliance Officer at the pre-award stage;

Post-award

- confirm that the information disclosed in the FCOI Screening Declaration is still current and, if not, update the Declaration; and
- ensure that all University Investigators involved in the PHS/NIH project are aware of, comply with and make any disclosures required under this Guidance, including completing the FCOI Confidential Disclosure Statement form for any SFIs identified in the FCOI Screening Declaration.

3.3 Head of School/Dean

- (a) Review disclosures of SFIs and determine if a FCOI exists (refer to Determination of FCOI below);
- (b) Manage FCOIs, including through the development and implementation of management plans and monitoring compliance (refer to Management Plans), with Institutional oversight/escalation to RGC and the Disclosure Review Committee (DRC) for a final decision.

- (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 the final expenditures report is submitted to NIH, or, where applicable, from other dates specified in NIH policy; and
- (d) Comply with any other obligations under the NIH policy.

3.4 Institutional responsibilities

- (a) Provide annual and ad hoc FCOI reports to PHS/NIH;
- (b) Maintain central 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 the final expenditures report is submitted to NIH, or, where applicable, from other dates specified in NIH policy;
- (c) Address non-compliance in accordance with this Guidance;
- (d) Take relevant corrective actions;
- (e) Receive, review and register changes to FCOIs;
- (f) Develop and implement Institutional-level processes to comply with PHS/NIH policy;
- (g) Report to NIH within 60 days of changes to FCOIs arising;
- (h) Provide Institutional-level monitoring and assurance; and
- (i) Record completion of training by all Investigators.

4. Training Requirements

- 4.1 Each Investigator must understand their responsibilities under this Guidance (including the responsibilities regarding disclosure of SFIs) and the NIH policy and must complete the NIH on-line tutorial:
 - (a) prior to engaging in PHS/NIH-Funded Research;
 - (b) at least once every 4 years; and
 - (c) immediately when any of the following circumstances apply:
 - this supplemental guidance or procedures relating to FCOI policies are revised in any manner that affects the requirements of Investigators;
 - An Investigator is new to the University, even if the PHS/NIH Funded Research has already begun; or
 - An Investigator is not in compliance with this supplemental guidance or a management plan, as determined by the Head of School/Director RGC.
- 4.2 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 RGC rgc@unsw.edu.au

5. Definition of Significant financial interest (SFI)

- 5.1 A financial interest consisting of one or more of the following interests of the Investigator (and 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 \$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;
- (b) 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 \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); and
 - (c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 5.2 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 federal, state, or local government agency, an institution of higher education as defined at [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical centre, or a research institute that is affiliated with an institution of higher education; or
 - (d) income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined at [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical centre, or a research institute that is affiliated with an institution of higher education.

6. Determination of FCOI

- 6.1 The relevant Investigator's supervisor (Head of School or Dean – Delegated Authority) determines, on behalf of the University, whether an FCOI exists for the purposes of the NIH policy.
- 6.2 The Delegated Authority must determine whether the significant financial interest declared by the Investigator may reasonably be said to be related to the PHS/NIH research by assessing whether the SFI:
- (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.
- 6.3 If the SFI is determined by the Delegated Authority to be related to the PHS/NIH research, the Delegated Authority must determine whether the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH research.
- 6.4 If the SFI is determined by the Delegated Authority 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 (see below).
- 6.5 The Head of School/Dean may involve the Investigator in the Delegated Authority(s)'s 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 by the Delegated Authority.

6.6 Advice can be sought from the [Research Integrity Unit](#)

7. Management Plans

- 7.1 Where a FCOI is identified, the Delegated Authority must develop and implement a management plan within 60 days of the FCOI being identified that specifies the actions that have been, and shall be, taken to manage such financial conflict of interest. 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) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - (c) 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;
 - (d) Modification of the research plan;
 - (e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - (f) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - (g) Severance of relationships that create financial conflicts.
- 7.2 The Delegated Authority must appropriately monitor compliance at the local level with any management plan until the completion of the PHS/NIH project.

8. Non-compliance and Remedies

- 8.1 In the event that an incidence of non-compliance or suspected non-compliance is identified, Investigators and Delegated Authority's must immediately:
- (a) report the non-compliance or suspected non-compliance to the [Research Integrity Unit](#); and
 - (b) take all necessary steps to retrospectively comply with this Guidance relating to disclosure, determination and management of SFIs.
- 8.2 The [Research Integrity Unit](#) will, within 120 days of detecting any suspected non-compliance, review the Investigator's activities and the PHS/NIH project under its research integrity processes in order to determine whether research misconduct may have occurred and 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 this review.
- 8.3 Where non-compliance relates to PHS/NIH research investigating the safety or effectiveness of a drug or device, the University may require the Investigators to disclose the FCOI in each public presentation and request an addendum to previously published outcomes relating to the research, and the Investigators must comply with this requirement.
- 8.4 Non-compliance with this Guidance, including failure to disclose SFIs or failure to comply with any management plan, may constitute research misconduct.
- 8.5 In the event of non-compliance with any requirements under this Guidance, the University may take corrective actions in accordance with applicable University and NIH policies and procedures, including withholding access to NIH funds and/or suspending project activity.

9. Record-keeping

- 9.1 Principal Investigators, Investigators and Delegated Authority's must create, maintain and store all local-level records relating to implementation of this Guidance for at least 3 years following the submission of the final report to the NIH (or such other period as required under the NIH policy), and in accordance with the University's record-keeping policies. In addition, the University will store and retain all relevant central records in accordance with NIH and University requirements.

10. Public accessibility requirements

- 10.1 This Guidance must be published on the University's public-facing website.
- 10.2 The University will, within 5 business days of a request, disclose requisite details of any FCOIs whenever such information is requested. Requests should be made to research.integrity@unsw.edu.au

11. Requirements regarding Subrecipients

- 11.1 If the University is the prime awardee, the University delegates responsibility for compliance with the NIH FCOI policy relating to identification, disclosure, determination and management of FCOIs to each sub-awardee, and will specify in any sub-awardee agreement all matters necessary to implement 42 CFR 50.604, including that the sub-awardee must:
- (a) comply with the requirements of the NIH FCOI policy;
 - (b) submit all requisite details of FCOIs to UNSW Sydney:
 - prior to the expenditure of funds; and
 - within 60 days of any subsequently identified FCOI;
 - (c) promptly notify the University of any management plan and suspected non-compliance; and
 - (d) provide a declaration that all FCOIs have been identified, disclosed and managed in accordance with NIH requirements.

Acknowledgements	
Legislative Compliance	NIH FCOI Policy to comply with the requirements of 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" (FCOI Regulation), as implemented in the 2011 Final Rule for grants and cooperative agreements.
University of Melbourne	Research Integrity & Misconduct Policy – PHS/NIH FCOI Requirements