

PHS/NIH Project Financial Conflict of Interest (FCOI) Requirements

Guidance issued under the Research Integrity and Misconduct Policy (MPF1318)



THE UNIVERSITY OF
MELBOURNE

This Guidance is issued under the Research Integrity and Misconduct Policy (MPF1318) 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) 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 NIH FCOI policy requires that the University identifies, discloses and manages the FCOI of grant recipients where we reasonably determine that an Investigator has a 'Significant Financial Interest' (SFI), related to an PHS/NIH-funded research project, that could affect the objectivity of PHS/NIH-funded research. In order to make this determination, Investigators must declare their Significant Financial Interests 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 differ from, and 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. Of particular note is that 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 Department or Dean act as the University's **Designated Official** to determine whether an 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, undertake FCOI training (must be undertaken at least every four years) on the Investigator's responsibilities regarding disclosure of SFIs, available through the [NIH FCOI Online Tutorial](#) (See Section below on Training requirements);
- (b) Assist the University's Principal Investigator to complete the University's FCOI Screening Form at the pre-award stage;
- (c) Disclose any and all identified Significant Financial Interests (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 University's FCOI Disclosure Form and submit to Head of Department/Dean, copied to RIC Compliance Officer at the post-award stage:
 - (i) prior to expenditure of PHS/NIH funding;
 - (ii) annually post-award;
 - (iii) within 30 days of a new SFIs arising during the course of an PHS/NIH project; and
 - (iv) within 30 days of new investigators joining the project;
- (d) Assist with the development of a management plan for any identified Significant Financial Interests 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

- (i) complete the FCOI Screening Form with respect to all University Investigators and submit the FCOI Screening Form to RIC Compliance Officer at the pre-award stage;

Post-award

- (ii) confirm that the information disclosed in the FCOI Screening Form is still current and, if not, update the Form; and
- (iii) 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 Disclosure Form for any Significant Financial Interests identified in the FCOI Screening Form.

3.3 Head of Department/Dean

- (a) Review disclosures of Significant Financial Interests 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 RIC;
- (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:
 - (i) this supplemental guidance or procedures relating to FCOI policies are revised in any manner that affects the requirements of Investigators;
 - (ii) An Investigator is new to the University, even if the PHS/NIH Funded Research has already begun; or
 - (iii) An Investigator is not in compliance with this supplemental guidance or a management plan, as determined by the Designated Official.
- 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 RIC Compliance Officer.

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 Department or Dean – **Designated Official**) determines, on behalf of the University, whether an FCOI exists for the purposes of the NIH policy.
- 6.2 The Designated Official 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 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.
- 6.4 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 (see below).
- 6.5 The Head of Department/Dean may involve the Investigator in the Designated Official(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 Designated Official.
- 6.6 Advice can be sought from the Office of Research Ethics and Integrity.

7. Management Plans

- 7.1 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 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 Designated Official 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 Designated Officials must immediately:
- (a) report the non-compliance or suspected non-compliance to the Office of Research Ethics and Integrity; and
 - (b) take all necessary steps to retrospectively comply with this Guidance relating to disclosure, determination and management of SFIs.
- 8.2 The Office of Research Ethics and Integrity 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 Designated Officials 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@unimelb.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 the University of Melbourne:
 - (i) prior to the expenditure of funds; and
 - (ii) 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.