

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

This Protocol is issued under Griffith University's [Responsible Conduct of Research Policy](#) to support compliance with the United States' Public Health Service / National Institutes of Health (**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 Protocol (including FAQs) are available on the NIH website, which also points to the FCOI Regulation that governs these requirements:

- [NIH FCOI Policy](#)
- [NIH FCOI FAQs](#)
- [42 CFR 50, Subpart F, Promoting Objectivity in Research](#) (FCOI Regulation)

This Protocol should also be read in conjunction with the [Conflict of Interest Policy](#), the [Australian Code for the Responsible Conduct of Research \(2018\)](#) and the [research integrity resources](#) produced by the University.

1.0 Purpose

The 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 (and those of the Investigator's spouse/ common law partner and dependent children).**

2.0 Scope

The requirements for **Investigators** set out in this Protocol 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. This definition includes:

- a. Staff members or adjuncts of Griffith University who are Investigators in PHS/NIH-funded research or identified as Investigators in applications for such funding regardless of whether the funding, or the application for funding, is Griffith-led.
- b. Researchers who are members of other institutions who are Investigators in Griffith-led PHS/NIH funded research or identified as Investigators in Griffith-led applications for such funding.
- c. Heads of Element who act as the **University's Designated Official** to determine whether an FCOI exists and implement and monitor management plans. In the case where a Head of Element is an Investigator, the Group PVC or such other person appointed by the Deputy Vice Chancellor

Research, will review disclosures under this Protocol (Designated Officials) or in the case of Investigators from other institutions, in accordance with the arrangements agreed with the Investigator's institution (see Subrecipient Requirements below).

The University's first named Investigator (**Principal Investigator**) has additional responsibilities.

3.0 Identifying Significant Financial Interests (SFI) and Financial Conflicts of Interest (FCOI)

3.1 Definition of SFI

- a. A SFI is a financial interest consisting of (for the Investigator or the Investigator's spouse or dependent children):
 - i. remuneration from any entity other than an Investigator's Institution, including salary or other payment for services, reimbursement for travel and accommodation or sponsored travel or income from intellectual property rights such as royalties from patents and copyright; or
 - ii. an equity interest in an entity (shares, share options or other ownership interest);
 - iii. where the aggregate value of such remuneration and any equity interest (in the case of publicly traded entities) in the preceding twelve months exceeds AUD5,000; and
 - iv. which is or may reasonably appear to be related to the Investigator's 'institutional responsibilities', which include:
 - A. research activities;
 - B. consultancies;
 - C. teaching;
 - D. professional practice;
 - E. memberships of boards and committees within the Investigator's institution; or
 - F. service on panels or Boards either on behalf of the institution or by virtue of the Investigator's academic or professional expertise.
- b. The term Significant Financial Interest or SFI 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. 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;
 - iii. income from seminars, lectures, or teaching engagements sponsored by a US 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

- iv. income from service on advisory committees or review panels for a US 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.

3.2 Definition of FCOI

- a. A Significant Financial Interest is not necessarily a Financial Conflict of Interest. A FCOI is an Investigator's SFI that is reasonably determined:
 - i. to be related to PHS/NIHS-funded research; and
 - ii. to have the potential directly and significantly to affect the design, conduct or reporting of the research.
- b. A SFI can be related to PHS/NIH-funded research if the financial interest could be affected by the PHS/NIH-funded research or the SFI is in an entity whose financial interests could be affected by the research. Whether an SFI has the potential to affect the design, conduct or reporting of the research, and thus constitute a FCOI, will depend on other considerations such as the Investigator's actual role in design, conduct or reporting of the research.

3.3 Determination of an FCOI

- a. The relevant Investigator's supervisor (Head of Element – Designated Official) determines, on behalf of the University, whether an FCOI exists for the purposes of the NIH policy.
- b. 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:
 - i. could be affected by the PHS/NIH research; or
 - ii. is in an entity whose financial interest could be affected by the PHS/NIH research.
- c. If the Significant Financial Interests is determined by the Designated Official to be related to the PHS/NIH research, the Designated Official must determine whether the Significant Financial Interests could directly and significantly affect the design, conduct, or reporting of the PHS/NIH research.
- d. If the Significant Financial Interest is determined by the Designated Official to both:
 - i. relate to the PHS/NIH research; and
 - ii. affect the design, conduct or reporting of the PHS/NIH research, it is an FCOI, and must be managed (see below).
- e. The Designated Official may involve the Investigator in the Designated Official'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.
- f. Advice can be sought from the University's Integrity and Privacy Officer.

4.0 Responsibilities

4.1 Responsibilities of all Investigators and Key Personnel

All Investigators and Key Personnel must:

- a. Prior to commencing any PHS/NIH funded research at the University, undertake FCOI training (must be undertaken at least every four years) on their responsibilities regarding disclosure of Significant Financial Interests, available through the [NIH FCOI Online Tutorial](#) (See Section below on Training requirements);
- b. Assist the University's Principal Investigator to complete the **Checklist for Conflict Identification (Appendix A)** at the pre-award stage;
- c. For successful projects, 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 **COI Disclosure Form** for review by the Head of Element, and development of a management plan if required:
 - i. prior to expenditure of NIH funding;
 - ii. annually post-award;
 - iii. within 30 days of a new Significant Financial Interest 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 that significantly affect the design, conduct or reporting of the PHS/NIH project;
- e. Comply with this Protocol 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.

4.2 Responsibilities of the Principal Investigator

The Principal Investigator is the University's first named investigator on the PHS/NIH grant. The Principal Investigator must comply with all of the above Investigator Responsibilities and in addition:

Pre-award

- a. complete the Checklist for Conflict Identification with respect to all University Investigators and submit the completed Checklist/s to preaward@griffith.edu.au at the pre-award stage;
- b. disclose all identified Significant Financial Interests in ethics application/s for the research project, if applicable.

Post-award

- c. confirm that the information disclosed in the **Checklist for Conflict Identification** is still current and, if not, update the Form; and

- d. ensure that all University Investigators involved in the PHS/NIH project are aware of, comply with and make any disclosures required under this Protocol, including completing the University's **COI Disclosure Form** for any Significant Financial Interests identified in the Checklist for Conflict Identification.

4.3 Responsibilities of the Head of Element (or other Designated Official)

- 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 the University's Integrity and Privacy Officer;
- 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.

4.4 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 Protocol;
- 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.

5.0 FCOI Management Plans

- a. Where an 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 conflicts of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
 - i. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
 - ii. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - iii. 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;

- iv. Modification of the research plan;
 - v. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - vi. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - vii. Severance of relationships that create financial conflicts.
- b. The Designated Official must appropriately monitor compliance at the local level with any management plan until the completion of the PHS/NIH project.

6.0 FCOI Training Requirements

- a. Each Investigator must understand their responsibilities under this Protocol (including the responsibilities regarding disclosure of Significant Financial Interests) and the NIH policy and must complete the NIH FCOI Online Tutorial:
- i. prior to engaging in PHS/NIH-Funded Research;
 - ii. at least once every 4 years; and
 - iii. immediately when any of the following circumstances apply:
 - A. this supplemental Protocol or procedures relating to FCOI policies are revised in any manner that affects the requirements of Investigators;
 - B. An Investigator is new to the University, even if the PHS/NIH Funded Research has already begun; or
- b. An Investigator is not in compliance with this supplemental Protocol or a management plan, as determined by the Designated Official.
- c. 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 Senior Manager, Research Grants in the Office for Research.

7.0 Requirements Regarding Subrecipients

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 Griffith University:
 - 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.

8.0 Non-compliance and Remedies

- a. In the event that an incidence of non-compliance or suspected non-compliance is identified, Investigators and/or Designated Officials must immediately:
 - i. report the non-compliance or suspected non-compliance to the University's Integrity and Privacy Officer and the Office for Research Ethics & Integrity Manager; and
 - ii. take all necessary steps to retrospectively comply with this Protocol relating to disclosure, determination and management of SFIs.
- b. The Research Ethics & Integrity Unit will, within 120 days of being informed of or 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.
- c. 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.
- d. Non-compliance with this Protocol, including failure to disclose SFIs or failure to comply with any management plan, may constitute research misconduct.
- e. In the event of non-compliance with any requirements under this Protocol, 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.

9.0 Record-keeping and Reporting

Principal Investigators, Investigators and Designated Officials must create, maintain and store all local-level records relating to implementation of this Protocol 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.

10.0 Public accessibility requirements

- a. This Protocol must be published on the University's public-facing website.
- b. 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 researchgrants@griffith.edu.au.
- c. Any person may request the following information concerning FCOIs relating to PHS/NIH-funded research:
 - i. the Investigator's role with respect to the research project;
 - ii. the name of the entity in which a SFI is held;
 - iii. the nature of that interest; and
 - iv. the approximate value of the interest or, if a value cannot be determined readily by reference to market prices or other measures of market value, a statement to that effect.
- d. Any request to provide information not specified above will be at the University's discretion.
- e. Requests may be submitted to researchgrants@griffith.edu.au.

CONFLICT OF INTEREST:

CHECKLIST FOR CONFLICT IDENTIFICATION

The purpose of this tool is to provide a checklist that you can work through when you are faced with a situation in which you think you might have an actual, perceived, or potential conflict of interest. This form is for your own personal use, but if after completing the form you have any doubts about whether or not you have a conflict of interest, you should complete the conflict of interest declaration form available on the University's [Conflict of Interest](#) website.

First steps

- 1) Describe the matter or issue being considered and the specific situation in which you are involved
- 2) Think about your professional duty as a researcher or staff member of the University

Making an assessment

In assessing whether you have an actual, perceived, or potential conflict of interest, it may be helpful to ask yourself the following questions. The test when assessing these situations is to ask yourself, 'could this conflict with my professional duties?'

What is the situation?

YES	NO	
<input type="checkbox"/>	<input type="checkbox"/>	Would I or anyone associated with me benefit from or be detrimentally affected by my proposed decision or action?
<input type="checkbox"/>	<input type="checkbox"/>	Could there be benefits for me in the future that could cast doubt on my objectivity?
<input type="checkbox"/>	<input type="checkbox"/>	Do I have a current or previous personal, professional or financial relationship or association of any significance with an interested party?
<input type="checkbox"/>	<input type="checkbox"/>	Would my reputation or that of a relative, friend or associate stand to be enhanced or damaged because of the proposed decision or action?
<input type="checkbox"/>	<input type="checkbox"/>	Do I or a relative, friend or associate of theirs stand to gain or lose financially in some covert or unexpected way?
<input type="checkbox"/>	<input type="checkbox"/>	Do I hold any personal or professional views or biases that may lead others to reasonably conclude that I am not an appropriate person to deal with the matter?
<input type="checkbox"/>	<input type="checkbox"/>	Have I contributed in a private capacity in any way to the matter my agency is dealing with?
<input type="checkbox"/>	<input type="checkbox"/>	Have I made any promises or commitments in relation to the matter?
<input type="checkbox"/>	<input type="checkbox"/>	Have I received a benefit or hospitality from someone who stands to gain or lose from my proposed decision or action?
<input type="checkbox"/>	<input type="checkbox"/>	Am I a member of an association, club or professional organisation or do I have particular ties and affiliations with organisations or individuals who stand to gain or lose by my proposed decision or action?
<input type="checkbox"/>	<input type="checkbox"/>	Could this situation have an influence on any future employment opportunities outside my current official duties?

YES	NO	
<input type="checkbox"/>	<input type="checkbox"/>	Could there be any other benefits or factors that could cast doubts on my objectivity?
<input type="checkbox"/>	<input type="checkbox"/>	Do I still have any doubts about my proposed decision or action?
<input type="checkbox"/>	<input type="checkbox"/>	<p>For NIH grant applicants and successful awardees:</p> <p>Do I have a Significant Financial Interest (SFI), as defined in Item 3.1 of the PHS/NIH Project Financial Conflict of Interest (FCOI) Protocol?</p> <p>If yes, you must immediately advise the Office for Research. If your grant is successful you will be asked to complete a COI declaration so a determination can be made by your Head of Element/Designated Official as to whether or not your SFI constitutes an FCOI that needs to be appropriately managed.</p>

What perceptions could others have?

- What assessment would a fair-minded member of the public make of the circumstances?
- Could my involvement in this matter cast doubt on my integrity or on my agency's integrity?
- If I saw someone else doing this, would I suspect that they might have a conflict of interest?
- If I did participate in this action or decision, would I be happy if my colleagues and the public became aware of my involvement and any association or connection?
- How would I feel if my actions were highlighted in the media?
- Is the matter or issue one of great public interest or controversy where my proposed decision or action could attract greater scrutiny by others?

Should I seek help?

YES NO

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Would a reasonable member of the community be confident of my ability to act impartially and in the interests of my profession and the University? |
| <input type="checkbox"/> | <input type="checkbox"/> | Do I feel a need to seek advice or discuss the matter with an objective party? |
| <input type="checkbox"/> | <input type="checkbox"/> | Is all the relevant information available to ensure a proper assessment? |
| <input type="checkbox"/> | <input type="checkbox"/> | Do I know what University policies require in relation to conflicts of interest? |
| <input type="checkbox"/> | <input type="checkbox"/> | Am I familiar with the tools and resources on the University's Conflict of Interest website about conflict of interest? |
| <input type="checkbox"/> | <input type="checkbox"/> | Do I understand the possible penalties that may apply if I proceed with an action or decision with an unresolved conflict of interest? |

Can I now make a decision?

These questions are designed to help you think about whether or not you have a financial conflict of interest, and whether you're aware of the policies, tools, and guidance material for conflict of interest, and the penalties that can apply if you do have an unresolved conflict.

There is no specific cutoff to the number of answers that qualify you as having a conflict. If after completing the exercise you feel that you do have an actual, perceived, or potential conflict, your next step should be to complete the conflict of interest disclosure form. If you are unsure of whether or not you have a conflict, you should review the resources provided on the University's [Conflict of Interest](#). If still uncertain, it is best to complete University's [COI Disclosure Form](#).

Adapted from CMC Qld and ICAC NSW resource "Managing Conflicts of Interest in the Public Sector" and the University of Melbourne resource "Conflict of interest: Checklist for conflict identification"

INFORMATION

Printable version (PDF) Downloadable version (Word)

Title	PHS/NIH Project Financial Conflict of Interest (FCOI) Protocol
Document number	2023/0001251
Purpose	<p>The 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.</p> <p>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.</p> <p>Additionally, the PHS/NIH requires regular and compulsory PHS/NIH FCOI training for all Investigators and continuous disclosure and management of identified FCOIs.</p> <p>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 (and those of the Investigator's spouse/ common law partner and dependent children).</p>
Audience	Staff
Category	Governance
Subcategory	Governance - Risk and Integrity
Approval date	27 January 2023
Effective date	27 January 2023
Review date	2026
Policy advisor	Senior Manager, Research Grants
Approving authority	Deputy Vice Chancellor (Research)

RELATED POLICY DOCUMENTS AND SUPPORTING DOCUMENTS

Legislation	42 CFR 50, Subpart F, Promoting Objectivity in Research (US FCOI Regulation)
Policy	NIH FCOI Policy Conflict of Interest Policy Australian Code for the Responsible Conduct of Research (2018)
Procedures	Research integrity resources Conflict of Interest website COI Disclosure Form
Local protocols	N/A
Forms	Conflict of Interest: Checklist for Conflict Identification