



Appendix: Instruction on Financial Conflict of Interest Requirements of US Federal PHS- and NIH-funded Research

This Instruction is issued by the Deputy Vice-Chancellor Research pursuant to powers to promote responsible research practices under the *Research Conduct Policy* (section 4(5)) [[Research Conduct policy / Document / Deakin Policy Library](#)] and powers to ensure institutional compliance with the conditions of external research funding.

Note: Capitalised words and phrases below, apart from proper names, are defined terms. Definitions appear in the relevant section.

1. Purpose of Instruction

To promote awareness of and compliance with the requirements of the US Federal Public Health Service ('PHS') and the National Institutes of Health ('NIH') in relation to Financial Conflicts of Interest ('FCOI') when applying for and administering research funding from the PHS/NIH and conducting research using such funding.

The requirements in this Instruction Appendix are intended to supplement and do not replace the requirements of the *Research Conduct Policy* and the *Conflict of Interest Procedure* [[Conflict of Interest procedure / Document / Deakin Policy Library](#)]

2. Overview of NIH FCOI Policy

The NIH promotes objectivity in research by establishing standards to provide that the design, conduct and reporting of research under NIH grants will be free from bias arising from Investigators' financial interests.

The full NIH Policy and related resources are published at the NIH website:

[Financial Conflict of Interest | grants.nih.gov](https://grants.nih.gov/financial-conflict-of-interest)

The governing US Federal Regulation (42 CFR 50 Subpart F) is available at:

[Title 42 Part 50 Subpart f - Code of Federal Regulations \(ecfr.io\)](https://www.ecfr.io/title-42/part-50/subpart-f)

The NIH requires that each institution proposing to obtain PHS/NIH funding for research has in place a written and enforced administrative process to identify and manage investigators' FCOIs with respect to all research projects for which NIH funding is sought or received.

This administrative process must involve disclosure and assessment of investigators' interests that may constitute FCOIs, management plans for identified FCOIs and procedures for monitoring

implementation of FCOI management plans, training for investigators, maintaining FCOI-related records, reporting FCOIs to the NIH, enforcement and remedies for non-compliance, addressing FCOI requirements for subrecipients, maintenance of records and public access to information.

3. Application

This Instruction applies to:

- a) *Academic staff members or honorary academic members of Deakin University ('Deakin')* 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 Deakin-led.
- b) *Researchers who are members of other institutions* who are Investigators in Deakin-led PHS/NIH funded research or identified as Investigators in Deakin-led applications for such funding.
- c) Officers of Deakin charged with administering applications for research grants and administering Deakin's obligations under the terms of awarded research grants (**DR Grants**)
- d) Heads of Investigators' Schools or Institutes or, in the case where a Head of School or Institute is an Investigator, to the Dean of Faculty or such other person appointed by the Deputy Vice-Chancellor Research, to review disclosures under this Instruction (**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).

4. Disclosure of Significant Financial Interests

1) Responsibilities of Investigators

- a) **Investigators** are persons responsible for the design, conduct or reporting of PHS/NIH-funded research projects or projects proposed for such funding.
- b) **Deakin's Lead Investigator** is the first named Investigator in an application for NIH funding submitted through Deakin.
- c) Investigators are required to disclose any financial interests of the Investigator, the Investigator's spouse and dependent children that 'reasonably appear to be related to the Investigator's institutional responsibility' (Significant Financial Interest ('SFI'), as detailed below) using the form provided for the purpose by DRGrants (*Deakin NIH SFI Declaration Form*):
 - i) At application stage, and no later than the time of application;
 - ii) During the period of an award:
 - (1) for any Investigator newly joining a project, within thirty days of joining the project;
 - (2) annually during the period of the Award; and
 - (3) for an existing Investigator acquiring or discovering a new SFI, within thirty days of discovering or acquiring the SFI.
- d) Deakin's Lead Investigator is required to liaise with all Investigators to ensure timely disclosure by Investigators in accordance with this Instruction.

2) Responsibility of DR Grants

Deakin's Research Grants Office is responsible for soliciting disclosures through Deakin's Lead Investigator at application stage, annually during the period of the award or when receiving notification from Deakin's Lead Investigator that a new Investigator is joining the project.

3) Meaning of 'Significant Financial Interest' (SFI)

- a) A SFI is a 'financial interest' of an Investigator or an Investigator's spouse or dependent children that consists in:
- i) remuneration from any entity other than the 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:
 - (1) research activities;
 - (2) consultancies;
 - (3) teaching;
 - (4) professional practice;
 - (5) memberships of boards and committees within the Investigator's institution; or
 - (6) service on panels or Boards either on behalf of the institution or by virtue of the Investigator's academic or professional expertise.
- b) A SFI does not include any of the following types of financial interest:
- i) salary, royalties or other remuneration paid by the Investigator's institution (i.e., Deakin in the case of Deakin Investigators);
 - ii) income from investment vehicles (such as mutual funds and superannuation funds), provided that the Investigator does not control the investment decisions made by these vehicles;
 - iii) income from seminars, lectures or teaching sponsored by US government agencies or US institutions of higher education, including academic teaching hospitals, medical centres or research institutes affiliated with a US institution of higher education (refer 20 U.S.C. 1001(a) for the definition of higher education institution) [[20 U.S. Code § 1001 - General definition of institution of higher education | U.S. Code | US Law | LII / Legal Information Institute \(cornell.edu\)](#)]; or
 - iv) income from service on review panels and advisory committees for US government agencies or US institutions of higher education (see above).

5. Financial Conflicts of Interest ('FCOI'): Reviewing SFI Disclosures and Determining and Managing FCOIs

1) Referral of SFI

Where a SFI is received by DR Grants, DR Grants will refer the SFI to the relevant Designated Official or request the DVCR to appoint a Designated Official (see above) and request the Deakin Research Integrity Unit in the Researcher Development portfolio (**Deakin Research Integrity**) to provide advice to the Designated Official.

2) What is a 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.
- c) An example of an Investigator's SFI being related to research is an Investigator receiving royalties from a pharmaceutical company for a pharmaceutical product which is being trialled for potentially new applications or where the product's possible negative side-effects are the subject of a trial. Whether this 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.
- d) If a FCOI is determined to exist, Deakin will put in place a FCOI Management Plan and submit a FCOI Report to the NIH.

3) Determining FCOIs

- a) SFIs are to be reviewed by the Designated Official (see section 3 above) who is to make a determination whether a FCOI exists and if so, develop, with the Investigator and Deakin's Lead Investigator, a FCOI Management Plan (section 6) and monitor the implementation of that plan.
- b) The Designated Official must review the SFI and:
 - i) determine whether the SFI is related to the PHS/NIH research, that is, the SFI or an entity in which the Investigator holds a SFI could be affected by the research; and, if so,
 - ii) assess whether the design, conduct or reporting of the research could be directly and significantly affected by the SFI; and, if so,
 - iii) *within sixty days of the date of disclosure of the SFI*, develop and implement a management plan, at least on an interim basis.
- c) The Designated Official must confer with Deakin Research Integrity, with the Investigator disclosing the SFI and Deakin's Lead Investigator, in relation to determining a FCOI and preparing a FCOI Management Plan.
- d) If the Designated Official finds a FCOI, the finding of a FCOI along with the FCOI Management Plan, must be reported promptly to DR Grants by the Designated Official to enable DR Grants to provide a FCOI Report to the NIH (see Section 11 - Reporting below).
- e) Where a FCOI is identified, the Investigator must also comply with the requirements of the Deakin *Conflict of Interest Procedure*, including declaring a conflict of interest and providing a management plan under that Policy. No finding in relation to a FCOI and a FCOI management plan pursuant to this Instruction replaces the requirements of the *Conflict of Interest Procedure*, and vice versa.

6. FCOI Management Plans

- 1) Where a FCOI has been found to exist, a management plan in writing must be approved by the Designated Official specifying the actions that have been or will be taken to manage the FCOI. The Designated Official should determine what actions are necessary and appropriate. These actions may include:
 - a) *Public disclosure*, for example in the context of presentations or publications of the results of the research;
 - b) Where a project involves human subjects, *disclosure to the participants* in accordance with Deakin's Research Conduct Policy and *Human Research Ethics Procedure* [[Human Research Ethics procedure / Document / Deakin Policy Library](#)];
 - c) Appointment of an *independent monitor* to ensure that the design, conduct and reporting of the project are free from any bias as a result of the FCOI;
 - d) *A change to the research plan*;
 - e) *A change of personnel* involved in the project or restrictions on personnel being involved in identified portions of the research;
 - f) *A reduction or elimination by the Investigator of the financial interest giving rise to the FCOI* through e.g., sale of equity or severance of a relationship through which remuneration is received.
- 2) The Designated Official is responsible for ensuring that compliance with a FCOI Management Plan is monitored through to the completion of the NIH research.

7. FCOI Training

- 1) Investigators must inform themselves of their responsibilities under this Instruction, including the SFI disclosure requirements, and the NIH Policy.
- 2) Investigators on PHS/NIH-funded research must complete the NIH on-line FCOI Tutorial ([FINANCIAL CONFLICT OF INTEREST - NEWEST \(nih.gov\)](#)):
 - a) prior to engaging in PHS/NIH-funded research;
 - b) within the term of PHS/NIH-funded research, every four years;
 - c) when an Investigator joins Deakin even if they have previously participated in the research before arrival;
 - d) where an Investigator has been found not to have complied with this Instruction (see section 8 below); or
 - e) whenever this Instruction is revised in a way that affects the requirements of Investigators.
- 3) Investigators must save the electronic certificate of completion of the NIH on-line tutorial and provide a copy on request to DR Grants.

8. Breach or Non-Compliance

- 1) If there has been a failure to comply with the provisions of this Instruction and the non-compliance relates to a delay or failure to disclose a SFI when required by the Instruction, and the SFI is determined to constitute a FCOI, or the non-compliance relates to a failure to comply with a FCOI Management Plan, the Investigator, Deakin Lead Investigator and Designated Official must immediately report the non-compliance or suspected non-compliance to Deakin Research Integrity.
- 2) Deakin Research Integrity will review the reported non-compliance, determine whether there has been non-compliance and if so, within 120 days of the determination of non-compliance,

conduct a retrospective review of the PHS/NIH-funded project to determine whether the research or any portion of it during the period of the noncompliance was biased in respect of the design, conduct or reporting of the research. If so, a Mitigation Plan must be prepared by Deakin Research Integrity in consultation with the Designated Official, the Investigator and Deakin Lead Investigator setting out how the bias is to be mitigated.

- 3) Regardless of any finding of bias, any failure to disclose a FCOI or to comply with a FCOI Management Plan may be subject to the Deakin *Research Integrity Breaches Procedure* [[Research Integrity Breaches procedure / Document / Deakin Policy Library](#)].
- 4) Remedies for non-compliance will be taken by Deakin in accordance with its policies and with the NIH policies and conditions of award, including, without limitation, measures to be set out in a Mitigation Plan.

9. Maintenance of Records

- 1) All records relating to implementation of this Instruction concerning disclosures of SFIs by Investigators, reviews of those disclosures and actions under this Instruction in response to reviews where a FCOI is identified must be managed and stored locally by Investigators, Deakin Lead Investigators and Designated Officials for at least three years from the date of submission of the final acquittal report for the PHS/NIH-funded research and in accordance with Deakin's Research Data Management Procedure.
- 2) DR Grants and Deakin Research Integrity will manage all central Deakin records in relation to this Instruction and PHS/NIH-funded research in accordance with *Deakin's Information and Records Management Policy* and NIH requirements.

10. Subrecipient Requirements

- 1) Where Deakin is the recipient of PHS/NIH-funding, Deakin will enter into a written agreement with any subrecipients.
- 2) Subrecipient institutions will be required either to certify that their policies comply with the NIH FCOI Policy or, failing that, to make an undertaking to solicit and report to Deakin disclosures of SFIs by the subrecipient's Investigators to enable Deakin to identify, manage and report FCOIs to the NIH.
- 3) If a subrecipient certifies that its policies comply with the NIH FCOI Policy, the subrecipient agreement will include a requirement for the subrecipient institution:
 - a) to comply with all of the requirements of 42 CFR 50.604 (Responsibilities of Institutions regarding Investigator financial conflicts of interest); and
 - b) to report identified FCOIs and FCOI Management Plans and any suspected non-compliance for its Investigators in a time frame that will enable Deakin to provide FCOI Reports to the NIH.

11. Reporting

- 1) DR Grants is responsible for submitting to the NIH all FCOI Reports required under the NIH Policy and terms of award. These include:
 - a) at the commencement of an award, before the expenditure of PHS/NIH funding;
 - b) annually, at the same time annual progress reports are due, reports about the status of FCOIs and changes to FCOI Management Plans; and

- c) within sixty days of any of the following events:
 - i) any changes to existing FCOIs;
 - ii) any new or newly identified FCOIs for existing Investigators; and
 - iii) any FCOIs identified for Investigators newly participating in a project FCOI.
- 2) DR Grants is also responsible for providing reports to the NIH on any findings of bias arising from a FCOI with the design, conduct or reporting of PHS/NIH-funded research showing actions taken or to be taken to mitigate the effects of the bias.

12. Public Access to Deakin FCOIs

- 1) This Instruction is to be published on Deakin's public web site.
 - 2) Any person may request the following information concerning FCOIs relating to PHS/NIH-funded research:
 - a) the Investigator's role with respect to the research project;
 - b) the name of the entity in which a SFI is held;
 - c) the nature of that interest; and
 - d) 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.
 - 3) Any request to provide information not specified above will be at Deakin's discretion.
 - 4) Requests may be submitted to research-integrity@deakin.edu.au.
 - 5) Deakin will respond to any request within five business days.
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Approved by:

Alfred Deakin Professor Julie Owens
Deputy Vice-Chancellor Research

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28th January 2022 _____

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Implementation and Review:

DR Grants in consultation with Deakin Research Integrity

Review Date:

Annually from the anniversary of the Effective Date or following any change to the NIH FCOI Policy