

US Financial Conflict of Interest Requirements

Purpose

This US Financial Conflict of Interest (FCOI) policy ensures that the Australian National University (ANU, or “the University”) staff are eligible to apply for US Public Health Service (PHS) and National Science Foundation (NSF) funding. This policy also ensures that ANU is compliant with the requirements of managing these Institution grants. This ANU US FCOI policy applies to Investigators applying for funding from NSF and the list of PHS funded agencies in appendix A. The Code of Federal Regulations (42 CFR 50, Subpart F) that applies to FCOI is administered by the US Department of Health and Human Services.

Overview

Several US federal agencies have their own requirements for disclosures related to their sponsored research projects. This US FCOI policy provides specific guidance on the requirements of the NSF and PHS agencies listed in appendix A and should be read in conjunction with the procedures and disclosure documents.

ANU staff seeking to apply for and hold PHS or NSF funding must comply with this policy at both the application and post award management stages.

Scope

This policy applies to all Investigators (as defined in this Policy) applying for or receiving US PHS or NSF grant funding and to the ANU Director, Research Services Division (RSD) who will manage any potential financial conflict of interests in conjunction with the Investigator’s supervisor. The Director, RSD also oversees institutional compliance with US federal funding.

It is important to note that, although ANU has a separate Policy on Conflict of Interest and Commitments, this US FCOI policy sits independent of that policy. This US FCOI policy is more prescriptive than the University’s Conflict of Interest and Commitment policy, and it applies only to Investigators as defined in this Policy. Disclosure solely under the Conflict of Interest and Commitment policy is not sufficient to meet the standards of the US FCOI policy due to the unique US regulatory environment.

To make US PHS and NSF federal-funded applications and grants more manageable, this policy covers both PHS and NSF. Although current NSF regulations specify a higher threshold for disclosing a Significant Financial Interest (SFI) than PHS, this policy identifies USD\$5,000 as the monetary threshold.

Definitions

Note all definitions are the same as the Financial Conflicts of Interest (FCOI) Policy, and terms defined in 42 CFR 50 Subpart F will have the same meaning in this Policy unless otherwise stated in this section.

“College Research Office” The local research hub responsible for liaising with academics, reviewing applications and submitting applications to the Research Funding and Development Office. Assist supervisors in monitoring Management Plans, as requested.

“Director, Research Services Division” is the Authorised Official Representative for the University. The signature of the Authorised Organisation Representative (AOR) certifies and oversees the Institution's compliance with the requirements of 42 CFR 50, Subpart F, including:

- Reviewing the FCOI disclosure forms, working with applicants to create an FCOI management plan and approving FCOI submissions at the time of application submission. The Director manages the post-award compliance and ensures the FCOI report is completed and submitted in accordance with the reporting timeframe.
- Ensuring that there is at the Institution an up-to-date, written and enforceable administrative process to identify and manage Financial Conflicts of Interest with respect to all research projects for which PHS and NSF funding is sought or received;
- Promoting and enforcing Investigator compliance with the regulation's requirements, including those pertaining to disclosure of Significant Financial Interests (SFIs); and
- Identifying and managing FCOIs and providing initial and ongoing FCOI reports to the Funding Agency consistent with this subpart.

“Disclosure of significant financial interests” means an Investigator's disclosure of significant financial interests to an Institution.

“Financial conflict of interest (FCOI)” means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of NSF or PHS-funded research.

“FCOI report” means an Institution's report of a financial conflict of interest to an NSF or PHS Awarding Component.

“Funding Agency” means the NSF or a PHS agency, not limited to appendix A.

“Investigator” refers to all staff members, regardless of title or position, who are responsible for the design, conduct or reporting of the PHS-/NSF-funded research, including sub-recipients, contractors, consortium participants, collaborators or consultants.

“Investigator Partner” refers to the spouse, same sex or de facto partner of an Investigator.

“Institution” refers to any domestic or foreign, public or private, entity or organisation (excluding a federal agency) that is applying for, or that receives, PHS or NSF research funding and in this Policy refers to ANU.

“Office of Research Integrity” RSD Office responsible for the management of FCOI records, oversight of integrity investigations and FCOI submissions to the relevant agency. Will maintain a central register for FCOI declarations and advise the Director, RSD on matters relating to compliance.

“Regulation or FCOI regulation” refers to 42 CFR Part 50 Subpart F, Promoting Objectivity in Research, which applies to both grants and cooperative agreements.

“Report” refers to the Institution's report of identified FCOIs to the Funding Agency.

“Research Funding and Development Office” review applications, make recommendations to Director, RSD and submit applications on Director's agreement.

“Significant Financial Interest (SFI)” is defined by 42 CFR Part 50 Subpart F, Sec. 50.603 as follows:

- a. A financial interest consisting of one or more of the following interests of the investigator (and those of the Investigator's spouse, same sex partner or de facto and dependent children) that reasonably appears to be related to the investigator's institutional responsibilities:
 - i. 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 purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, board sitting fees);
 - 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;

- ii. 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 USD \$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); or
 - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 - iv. Disclose positions at other institutions, honorary or paid that include but are not limited to sitting fees, per diem or expenses, funding for research etc.
- b. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (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, 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organiser, the destination and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
- c. Significant Financial Interest does not include the following types of financial interests:
- v. Salary, royalties, or other remuneration paid by ANU to the Investigator if the Investigator is currently employed or otherwise appointed by ANU,
 - vi. the ANU intellectual property rights assigned and agreements to share in royalties related to such rights;
 - vii. If primarily employed by a US higher education body, the income from a US higher education body via teaching or via a teaching hospital.

“Staff member” means a person who is employed by ANU, or who is given Academic Title or who has official visiting status as per the Academic Title Conferral Policy/Procedure.

“Sub-recipient” An external entity that receives a sub award through ANU to conduct research as per section 200.93 of the Uniform Guidance.

“Supervisor” will normally be the Head of the academic unit in which the staff member is employed as per the Procedure: Appointment of supervisors.

The Australian National University US Financial Conflict of Interest Policy

Principles that apply to managing a Conflict of interest

- **Register:** Disclose and establish the details of the conflict
- **Restrict:** Restrict the Staff member's involvement or actions in relation to the matter
- **Recruit:** Recruit an objective third party to oversee processes associated with the matter
- **Remove:** The individual that the interest relates to can remove themselves from involvement in the matter.
- **Relinquish:** The individual and/or any related parties may relinquish any interest that is contributing to, or creating, a conflict.
- **Resign:** The individual involved in a conflict can resign, thus eliminating the conflict. It is noteworthy that this is an extreme measure and should only be used when all other reasonable options have been exhausted.

Policy statement

1. This policy requires that Investigators disclose to the Institution, in accordance with the FCOI Procedure, all Significant Financial Interests that would reasonably appear to be related to the Investigator's institutional responsibilities which include: research and other scholarly activities; clinical care activities; teaching or educational activities; and administrative activities.
2. A condition of submitting an application is that all investigators applying for PHS or NSF funding complete the ANU US FCOI Disclosure form prior to the time of application. The Investigator/s must disclose all Significant Financial Interests or certify to their absence at the time of the application.
3. The lead ANU Investigator on a PHS- or NSF-funded project is responsible for ensuring all Investigators involved in that project have fulfilled their FCOI declaration responsibilities.
4. ANU must ensure that if there are Significant Financial Interests related to the funded research, these Significant Financial Interests are examined and dealt with according to institutional and funding agency policies on conflict of interest. A personal financial interest with an external entity would be reasonably considered related to an Investigator's research study in circumstances such as the following:
 - The external entity sponsors research at ANU in which the Investigator is directly involved
 - The external entity has financial interests that could reasonably be considered to have a potential influence on the design, conduct or reporting of Investigator's research/scholarship

- The external entity has a reasonable possibility of being financially affected by Investigator's research/scholarship
 - The external entity makes gifts to ANU that benefit Investigator's research/scholarship (including equipment gifts or loans)
 - The external entity makes a product that is under study in research in which Investigator is involved
 - The external entity licenses ANU intellectual property in which Investigator has a financial interest
 - The external entity sponsors or makes a product that is under study in human subjects in which Investigator is directly or indirectly involved
5. The Director, Research Services Division is responsible for ensuring that there are appropriate procedures in place for the review of all such disclosures to determine whether there is a Financial Conflict of Interest and for managing, reporting and monitoring any such Financial Conflict of Interest.
 6. Procedures and forms will be made available for Investigators in making their declaration on the ANU Funding Opportunities website.

Management of information

7. A central register of all interests will be established and maintained in accordance with the University's FCOI Procedure. The Director, RSD, Office of Research Integrity and supervisors across ANU will have access to the register for their staff and the relevant investigators disclosed information. Investigators will be responsible for ensuring their FCOI declaration is reviewed for accuracy/currency on at least an annual basis.
8. Staff members responsible for the submission and management of FCOI through a Funding Agency portal will also have access to the central register to ensure ANU meets its institutional obligations to the Funding Agency.
9. Information provided to US agencies will be stored and accessed in accordance with US legislation. ANU cannot guarantee information will be kept in accordance with Australian Privacy law.

Disclosure of the FCOI to Funding Agencies

10. Details of the FCOI may be disclosed by the Office of Research Integrity at RSD to US PHS Agencies or the NSF according to their policies. It may also be disclosed to other individual parties requesting this information as per 42 CFR section §50.605 (5).
11. The information that ANU makes available via written response to any requestor within five business days of a request, shall include, at a minimum, the following:
 - the Investigator's name;
 - the Investigator's title and role with respect to the research project;

- the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and
- the approximate dollar value of the significant financial interest (US dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value

12. If the Investigator revokes permission for the submission of the FCOI information or does not comply with updating their FCOI details in accordance with the Funding Agency FCOI policy, ANU may terminate or suspend the grant due to failure to meet the terms and conditions of the grant.

Sub-recipients

13. Sub-recipient institutional policies must be assessed by the Research Services Division to determine if their institutional policy complies with the FCOI Regulations at application stage. If not, the sub-recipient must agree to follow the University's FCOI policy.

Compliance

14. ANU regards non-compliance with this policy as a serious matter and, depending on severity and impact of any instances of non-compliance, will take appropriate disciplinary action.

15. Failure to comply with this policy and any of the associated procedures will constitute a breach of the University's [Code of Conduct](#) and may be dealt with as either misconduct or serious misconduct in accordance with the [Australian National University Enterprise Agreement 2017-2021](#).

16. If undeclared FCOIs emerge, the relevant US agency will be notified and the undisclosed FCOIs may be published in accordance with mitigation measures. For example, journals of published material may be contacted with a disclosure update for their publication.

17. Although current NSF regulations specify a higher threshold for Significant Financial Interest than PHS, ANU policy identifies USD\$5,000 as the monetary threshold.

Training

18. ANU will provide training to all Investigators regarding Financial Conflict of Interest in accordance with the FCOI Procedure.

Delegations relevant to this policy

- **000326:** Submit applications for grants, research contracts or consultancies on behalf of the University to any funding agency.

- **000327:** Sign all grant agreements and research contracts (excluding contracts involving the commercialisation of IP).
- **000328:** Sign consultancy agreements.
- **000329:** Determine the level and extent of the University's involvement in a CRC, partnership, joint venture or other formal research collaboration where the University contributes cash or in-kind.
- **000330:** Sign contracts involving the commercialisation of IP within portfolio responsibilities.
- **000331:** Sign non-disclosure agreements relating to ANU Intellectual Property.
- **000332:** Sign materials transfer agreements relating to ANU Intellectual Property.

Review

19. This policy will be reviewed every four years by the Director, Research Services Division and the Corporate Governance and Risk Office. Next review must be completed by 30 October 2024.

Appendix A – List of Public Health Services Funded Agencies

Agencies

- [National Institutes of Health \(NIH\)](#)
- [Food and Drug Administration \(FDA\)](#)
- [Substance Abuse and Mental Health Services Administration \(SAMHSA\)](#)
- [Agency for Healthcare Research & Quality \(AHRQ\)](#)
- [Agency for Toxic Substances and Disease Registry \(ATSDR\)](#)
- [Centers for Disease Control and Prevention \(CDC\)](#)
- [Health Resources and Services Administration \(HRSA\)](#)
- [Indian Health Service \(IHS\)](#)

Offices

- [Office of Global Affairs \(OGA\)](#)
- [Office of the Assistant Secretary for Preparedness and Response \(OASPR\)](#)
- [Office of the Assistant Secretary for Health \(ASH\)](#)