



Procedure: US Financial Conflict of Interest

Process and procedures developed by RSD Research Funding & Development Office (RFDO)

Purpose

This Procedure sets out the process for complying with the Australian National University's (ANU or "the University") US Financial Conflict of Interest (FCOI) Requirements. All participants in relevant funded projects including staff members, supervisors and the Director, Research Services Division (RSD) have a role in adhering to the policy and following process when applying for a grant through a National Science Foundation (NSF) or Public Health Service (PHS) agency. For the full list of PHS agencies, see appendix A.

Definitions

Note all definitions are the same as the Financial Conflicts of Interest (FCOI) Policy, and terms defined in in 42 CFR 50 Subpart F will have the same meaning in this Procedure 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" (Director, RSD) is the Authorised Official Representative for the Australian National 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 in effect 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 possible 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 disclosure 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 researchers at ANU and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of NSF- or PHS-funded research, including subgrantees, contractors, consortium participants, collaborators, or consultants.

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

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

“Office of Research Integrity” RSD Office responsible for the management of FCOI records, review of FCOI submissions, oversight of integrity investigations and FCOI submissions to the relevant agency.

“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. 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 subaward 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.

Procedure

Overview of Process

US funding and the need for disclosing Financial Conflicts of Interest (FCOI)

1. The US FCOI policy requires that, for each proposal submitted to a PHS Funding Agency or the NSF, Investigators certify that they have appropriately disclosed any Significant Financial Interests to ANU.
2. The Investigator/s must disclose to the Director, RSD all significant financial interests (as defined) of the Investigator and the investigator’s partner and dependents at the time of the application, at least annually during the period of the award and within 30 days of discovering or acquiring a new significant financial interest.
3. All investigators applying for PHS or NSF funding must complete the ANU US FCOI Disclosure Form at the time of application. The Investigator/s must disclose all significant financial interests or certify to their absence at the time of the application.
4. The lead Institution Investigator on a project is responsible for ensuring all investigators have fulfilled their declaration responsibilities.
5. These Significant Financial Interest disclosures must be updated at least annually and within thirty days of entering into a new relationship with a company/organisation or discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI. ANU US FCOI Disclosure Form will be used to submit updates.
6. Before an award can be accepted, the Director, RSD must determine whether the SFI is deemed to be a Financial Conflict of Interest.
 - If an FCOI is determined to exist, then a Management Plan detailing how the conflict will be managed, reduced or eliminated must be developed and implemented by the Director, RSD and Investigator’s Supervisor in consultation with the Investigator. At the Supervisor’s request, the College Research Office may be required to enforce the Management Plan.
 - The Management Plan may need to be submitted to the Funding Agency annually. This will be submitted by Office of Research Integrity on the Investigator’s behalf.

Training

7. ANU will establish and make FCOI training available for researchers.
8. Named Investigators are required to complete FCOI training:
 - a. Prior to submission of the application to the funding agency;
 - b. At least every four years;
 - c. Immediately if:
 - i. The institutional policy is revised
 - ii. There are new Investigators working on a NSF or PHS funded project
 - iii. An Investigator is not compliant with the policy or management plan.
9. The following people are required to complete FCOI training every four years:
 - a. Staff in Office of Research Integrity
 - b. Director, Research Services Division
 - c. College Research Office managers, as required.
10. All staff named in the NSF- or PHS-funded application, participating in the research and management of the funds will also complete the following training, including the quiz, print off the certificate and submit it to the Office of Research Integrity via their College Research Office: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

Pre-award disclosure process

At application Stage: Process for declaring a US FCOI at ANU

11. The Investigators applying for PHS or NSF funding should review the ANU FCOI website that outlines the policy, procedures and disclosure form requirements.
12. The Investigator(s) is responsible for disclosing information in accordance with ANU Policy on US Financial Conflict of Interest using the US FCOI Disclosure Form.
13. If the Investigator decides to proceed with the application, they must complete the FCOI training, then submit to the College Research Office:
 - i. Certificate of completion of FCOI training
 - ii. Completed US FCOI Disclosure Form
 - iii. Application to Funding Agency
 - iv. Delegate approval through Costing, Pricing, and Approval Tool.
 - v. Sub-recipient FCOI disclosure form (only if a sub-recipient is participating)
14. The College Research Office will submit the certificate, form, application and delegate approval to preaward.rsd@anu.edu.au for the application to be reviewed and endorsed for submission.
 - a) Application and US FCOI Disclosure Form are reviewed by Director, RSD and submitted to Funding Agency. On the Director, RSD behalf, the Deputy Director of RSD who is the head of Office of Research Integrity submits initial US FCOI Disclosure Form to Funding Agency as required. Research Funding and

Development Office to submit application to the Funding Agency on the Director, RSD behalf.

Managing Sub-recipients

15. College Research Offices will provide potential sub-recipient institutions with the sub-recipient FCOI disclosure form for completion. Sub-recipients must complete and submit the sub-recipient disclosure form via the College Research Office to preaward.rsd@anu.edu.au.

16. If the sub-recipient does not have a PHS FCOI policy or it does not meet the regulation requirements of 42 CFR 50 subpart F, the sub-recipient must agree to comply with ANU FCOI policy, undertake training and manage reporting in accordance with ANU policies and procedures.

Post-award management

Acceptance stage

17. In order to accept the award, the Director, RSD will review the US FCOI Disclosure Form against the FCOI policy.

18. The Deputy Director of RSD and head of Office of Research Integrity will review the US FCOI Disclosure Form, make recommendations to the Director, RSD and log the submission for potential post award management in the FCOI register and save the disclosed FCOI information in ERMS.

19. If required, the Director, RSD will put in place a Management Plan. The Management Plan must incorporate the conditions or restrictions to manage a FCOI and might 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.

20. The Director, RSD will provide the Office of Research Integrity, Supervisor and the Investigator copies of the FCOI Management Plan.

Prior to the use of funds

21. Prior to the use of award funds, the Office of Research Integrity is required to report the FCOI and the approved management plan to the Funding Agency.
22. While the Office of Research Integrity will hold all records for three (3) years past the date of final expenditure (or such other dates as specified in the Regulations where applicable), the Investigator and the Investigator's Supervisor are responsible for maintaining accurate records.
23. Investigators, via their College Research Office, must:
 - i. update yearly their US FCOI Disclosure form and submit to it to the Director, RSD;
 - ii. Disclose within thirty (30) days to the Director, RSD any new SFI that arise during the course of the awarded grant; and
 - iii. Within sixty (60) days of identification for an Investigator who is newly participating in the project associated with the awarded grant, submit a US FCOI Disclosure Form to the Director, RSD who will review to see if a management plan is needed.
24. As a part of the US Quarterly Reports process, Investigators must certify that they have adhered to the FCOI policy.

Institutional Disclosure requirements (§50.605(5)(ii)(iii))

25. The Office of Research Integrity on behalf of the Investigator and Director, RSD will provide the Funding Agency copies of the FCOI Reports throughout the life of the grant as per the contract and pursuant to §50.605(b). These FCOI Reports include the FCOI disclosed and the management plans.
26. Within 60 Days of commencing on a NSF or PHS funded project, a new Investigator will need to complete a US FCOI Disclosure Form that has been reviewed by the Director, RSD.
27. If it emerges during or after completion of the grant that undeclared FCOIs emerge, the agency will be notified, and a non-compliance review will be undertaken.
28. Research Integrity Office will ensure that in accordance with 42 CFR 50.605(a)(5)(i)-(iv), named Investigators FCOI most up-to-date details will be made available within five (5) calendar days of a written request. Be updated within sixty (60) days of a new FCOI and remain available for three (3) years.
29. The FCOI policy and procedure will be made available within five (5) business days of a written request.

Institutional process for reviewing FCOI that are non-compliant:

30. The Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any NSF- or PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
31. If bias is found, the report must be provided to the awarding NSF or PHS Funding Agency.
32. This review will be led by the Director, RSD, in consultation with the Investigator's Supervisor and other officials as required. This review will occur in accordance with the ANU Research Misconduct Policy.

Oversight by the Authorised Official Representative, Director of RSD.

33. The Director, RSD is the ANU Authorised Official Representative. The Director, RSD is responsible for reporting to the US Government for all US Federal funding and providing oversight to ensure the administration of the grants.
34. Investigators receiving US Federal Funding submit Quarterly Investigator Reports to RSD on their projects. As a part of the US Quarterly Reports process Investigators will certify they have adhered to the FCOI policy.

Misconduct review will be undertaken in accordance with §50.605, which is outlined in the ANU [Responding to allegations of scientific misconduct involving US PHS research grants](#).

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 \(ASH\)](#)