**US Financial Conflict of Interest Framework**

## Purpose

This US Financial Conflict of Interest (FCOI) framework ensures that the Australian National University (ANU, or “the University”) researchers are eligible to apply for, and hold US National Science Foundation (NSF) funding, Public Health Service (PHS) funding, or funding from non-PHS US funding agencies using the PHS regulations (including FCOI) in their award terms. This framework also ensures that ANU is compliant with the requirements of managing these institution grants. The Code of Federal Regulations ([42 CFR 50, Subpart F](https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-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 framework provides specific guidance on the requirements of the NSF, [PHS agencies](https://thefdp.org/default/fcoi-clearinghouse/fcoi-agencies/), or non-PHS agencies using the PHS regulations in their award terms. Hereinafter “PHS” refers to both PHS agencies and the non-PHS agencies using PHS regulations.

This framework should be read in conjunction with the [procedure and the disclosure form](https://services.anu.edu.au/research-support/funding-opportunities/us-financial-conflict-of-interest-regulation).

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

## Scope

This framework applies to all investigators (as defined in this framework) applying for or receiving US PHS or NSF grant funding and to the ANU Director, Research Services Division (RSD) who manages 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 framework is independent of that policy. The US FCOI framework is more prescriptive than the University’s Conflict of Interest and Commitment framework, and it applies only to investigators as defined in this framework. Disclosure solely under the Conflict of Interest and Commitment framework is not sufficient to meet the standards of the US FCOI framework due to the US regulatory requirements.

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

## Definitions

Note all definitions are the same as the Financial Conflicts of Interest (FCOI) Procedure, and terms defined in [42 CFR 50 Subpart F](https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F) have the same meaning in this framework unless otherwise stated in this section.

**College Research Office** is the local research hub that liaises with academics, reviews and submits applications to the Research Funding and Development Office. It also assists supervisors in monitoring management plans.

**Director, Research Services Division** (RSD) is the Authorised Official Representative (AOR) for the University. The AOR certifies and oversees the University’s compliance with the requirements of [42 CFR 50, Subpart F](https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F) and:

* reviews FCOI disclosure forms, works with applicants to create an FCOI management plan and approves 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;
* ensures there is an University up-to-date, written and enforceable administrative process to identify and manage FCOIs with respect to all research projects for which PHS and NSF funding is sought or received;
* promotes and enforces investigator compliance with regulation requirements, including those pertaining to disclosure of Significant Financial Interests (SFIs); and
* identifies and manages FCOIs and provides 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 the University.

**ERMS** means ANU Electronic Records Management System, a central repository for the management of electronic records.

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

**FCOI report**means the University’s report of a financial conflict of interest to NSF or PHS agencies.

**Funding agency** means the NSF or PHS agency or non-PHS using the PHS regulations in their award terms.

**Investigator** refers to all researchers, 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 framework refers to ANU (the University).

**Regulation or FCOI regulation** refers to [42 CFR Part 50 Subpart F, ‘Promoting Objectivity in Research’](https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F), which applies to both grants and cooperative agreements.

**Report** refers to the University’s report of identified FCOIs to the funding agency.

**Research Funding and Development Office** (RFDO) review applications, make recommendations to Director, RSD and submit applications with the Director’s agreement.

**RSD compliance team** is the office responsible for the management of FCOI records, oversight of integrity investigations and FCOI submissions to the relevant agency. **RSD maintains a central register for FCOI declarations and advises the Director, RSD on matters relating to compliance.**

**Significant Financial Interest (SFI)** is defined by [42 CFR Part 50 Subpart F, Sec. 50.603](https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F/section-50.603)as follows:

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 appear to be related to the investigator’s institutional responsibilities:

* 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;
* 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);
* intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; 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.;
* 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)](https://www.govinfo.gov/content/pkg/USCODE-2012-title20/html/USCODE-2012-title20-chap28-subchapI.htm); an academic teaching hospital; a medical centre or a research institute that is affiliated with an institution of higher education. The institution's FCOI framework 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 framework, the Director, Research Services 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.
* Significant Financial Interest does not include the following types of financial interests: salary; royalties or other remuneration paid by ANU to the investigator if the investigator is currently employed or otherwise appointed by ANU; ANU intellectual property rights assigned and agreements to share in royalties related to such rights; 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 [framework](https://policies.anu.edu.au/ppl/document/ANUP_000417)/[procedure](https://policies.anu.edu.au/ppl/document/ANUP_000647)**.**

**Sub-recipient** is an external entity that receives a sub award through ANU to conduct research as per [section 200.93](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=94cfef7a55e73c72dcda8246e6cc2bec&mc=true&n=pt2.1.200&r=PART&ty=HTML#se2.1.200_19) of the [Uniform Guidance](https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title02/2cfr200_main_02.tpl).

**Supervisor** will normally be the head of the academic unit in which the researcher is employed as per the Appointment of Supervisors [procedure](https://policies.anu.edu.au/ppl/document/ANUP_000645).

## Framework statement

1. The principles that apply to managing a conflict of interest are:
* **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 is only used when all other reasonable options have been exhausted.
1. T**his framework 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 activiti**es; 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](https://services.anu.edu.au/files/document-collection/Final%20ANU%20US%20FCOI%20Disclosure%20Form_v2.pdf) 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 considered to be 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;
	* has financial interests that could be considered to have a potential influence on the design, conduct or reporting of investigator's research/scholarship;
	* has a possibility of being financially affected by the investigator's research/scholarship;
	* makes gifts to ANU that benefit the investigator's research/scholarship (including equipment gifts or loans);
	* makes a product that is under study in research in which the investigator is involved;
	* licenses ANU intellectual property in which the investigator has a financial interest; and
	* sponsors or makes a product that is under study in human subjects in which the investigator is directly or indirectly involved.
5. RSD Director 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 guidelines are available for investigators in making their declaration on the following** [website](https://services.anu.edu.au/research-support/funding-opportunities/us-financial-conflict-of-interest-regulation)**.**

# Management of information

1. A central register of **all interests is established and maintained in accordance with the University’s FCOI procedure. RSD Director, RSD compliance team, and supervisors across ANU have access to the register for their staff and the relevant investigators disclosed information. Investigators are responsible for ensuring their FCOI declaration is reviewed for accuracy/currency on at least an annual basis.**
2. **Staff members responsible for the submission and management of FCOI through a funding agency portal also have access to the central register to ensure ANU meets its institutional obligations to the funding agency**.
3. Information provided to US agencies is stored in ERMS and accessed in accordance with US legislation. The ANU cannot guarantee information provided to the funder will be kept in accordance with Australian Privacy law.

# Disclosure of the FCOI to Funding Agencies

1. **Details of the FCOI may be disclosed by RSD compliance team 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)](https://www.ecfr.gov/cgi-bin/text-idx?node=sp42.1.50.f&rgn=div6#se42.1.50_1605).
2. **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
1. **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’s FCOI framework, ANU may terminate or suspend the grant due to failure to meet the terms and conditions of the grant.**

# Sub-recipients

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

# Compliance

1. ANU regards non-compliance with this framework as a serious matter and, depending on severity and impact of any instances of non-compliance, will take appropriate disciplinary action.
2. Failure to comply with this framework and any of the associated procedures constitutes a breach of the University’s [Code of Conduct](https://policies.anu.edu.au/ppl/document/ANUP_000388). It may be dealt with as either misconduct or serious misconduct in accordance with the [Australian National University Enterprise Agreement](https://services.anu.edu.au/human-resources/enterprise-agreement) , or [ANU academic integrity rule](https://services.anu.edu.au/learning-teaching/academic-integrity/academic-integrity-rule-2021#:~:text=Academic%20integrity%20is%20a%20core,as%20a%20community%20of%20scholars.&text=The%20Academic%20Integrity%20Rule%202021,of%20the%20academic%20integrity%20principle.).
3. **If undeclared FCOIs emerge, the relevant US agencies are 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.**

# Training

1. **Investigators must complete training regarding financial conflict of interest in accordance with the FCOI procedure.**

# Delegations relevant to this framework

* **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

1. This framework 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.