

Akros NIH FCOI Policy

The policy applies to National Institutes of Health (NIH) awards, either to Akros as prime or a subcontractor.

The policy applies to any staff involved in or responsible for the design, implementation, or reporting of research funded by the NIH which including (but not limited to):

- Principal Investigators (PIs)
- Co-Investigators
- External collaborators or consultants

For the purpose of this guidance and the NIH policy, all such individuals are referred to as 'Investigators'.

Under the NIH Conflict of Interest Policy, Investigators must complete the online NIH FCOI tutorial prior to engaging in research related to any NIH grant and at least every 4 years.

See below NIH guidance for further instruction.

NIH Financial Conflict of Interest

The NIH is committed to preserving the public's trust that the research NIH supports is conducted without bias and with the highest scientific and ethical standards. Learn about requirements for managing and reporting investigator financial conflicts of interest.

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The HHS regulation [42 CFR Part 50 Subpart F](#), Promoting Objectivity in Research (FCOI regulation), establishes standards that provide a reasonable expectation that the design, conduct, or reporting of NIH-funded research (grants and cooperative agreements) will be free from bias resulting from any Investigator's conflicting financial interest. NIH requires recipient [institutions](#) and their investigators (except Phase I [SBIR/STTR](#) applicants and recipients) to fully comply with all FCOI requirements. If the Institution carries out the NIH-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution must take reasonable steps to ensure that any subrecipient Investigator complies with FCOI requirements. The [Final Rule](#), including the Preamble to the Final Rule, was published in the Federal Register, Vol. 76, No. 165 on August 25, 2011.

Key Definitions

Investigator

The PD/PI and any other person, regardless of title or position who is responsible for the design, conduct, or reporting of NIH-funded research, or proposed for such funding, and which may include for example, collaborators or consultants. Includes investigators who plan to participate in or who participate in NIH-funded research.

FCOI

A financial conflict of interest exists when the institution's designated official(s) reasonably determines that an [investigator's significant financial interest \(SFI\)](#) could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. The institution is required to review each Investigator SFI disclosure to determine if a SFI:

1. is related to the NIH-supported research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest could be affected by the research)

and

2. could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

Significant Financial Interest

See FCOI [regulatory definition of SFI](#) including NIH's FAQs [D.8.](#), [E.9.](#) and [E.20.](#)

Highlights of the FCOI Regulation

When submitting a grant application or receiving a grant as a result of an application, the signature of the [Authorized Organization Representative \(AOR\)](#) certifies the applicant institution's full compliance with all of the requirements of the FCOI regulation, including:

1. Existence of institutional policy and process. There is in effect at the Institution an up-to-date, written and enforced administrative process and policy to identify and manage FCOI for all NIH-funded grants and cooperative agreements, excluding Phase I [SBIR/STTR](#) applications and awards.
2. Accessibility of institutional policy and submission to NIH. Institutions must post their FCOI policy on their publicly accessible Web site and [must submit their FCOI policy](#) to the NIH via the [eRA Commons Institution Profile \(IPF\) Module](#).
3. Institutional training of investigators. The Institution [must train their Investigators](#) (and ensure subrecipient Investigators are trained) about the FCOI regulation, the Institution's policy, and the Investigator's responsibility to fully disclose all domestic and foreign SFIs (and those of their spouse and dependent children) that are related to their [institutional responsibilities](#). Refer to NIH's [FCOI Training](#) website for training resources institutions may use to train Institutional officials and Investigators about the FCOI regulation, including other FCOI-related topic areas.
4. Investigator disclosures. Investigators must disclose all domestic and foreign SFIs that are related to the Investigator's [institutional responsibilities](#) (i.e., professional responsibilities on behalf of the institution, such as research, research consultation, teaching, professional practice, etc.) that are received from and/or held in an entity outside the institution. Note: institutional policies may provide a threshold for investigator disclosure related to certain types of SFIs (see FAQs [E.9.](#) and [E.20.](#)).
 - Disclosures of foreign financial interests. It is important to note that disclosure of foreign financial interests differs from disclosure of domestic financial interests. Investigators, including subrecipient Investigators, must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

5. Institutions determine FCOIs. The institution is required to review each Investigator SFI disclosure to determine if a SFI is:
 - related to the Investigator's NIH-funded research. An SFI is related to NIH-funded research when the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research, and
 - a FCOI. An SFI is considered a FCOI when the SFI could directly and significantly (i.e., have a material effect) affect the design, conduct, or reporting of the NIH-funded research.
6. Management and reporting of FCOIs. When the institution determines that an FCOI exists, the Institution must report to the NIH awarding Institute or Center through the submission of an initial (Original) and annual FCOI report using the [eRA Commons FCOI Module](#). The institution must also manage the identified FCOI.
7. Maintenance of records. The Institution must maintain records of and, when requested, will promptly [make information available](#) to the NIH relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI.

For full FCOI requirements, see the [NIH Grants Policy Statement, Section 4.1.10](#), Financial Conflict of Interest and [42 CFR 50 Subpart F](#), Promoting Objectivity in Research.

Elements of an FCOI Report

The FCOI regulation requires institutions to submit the following information when reporting an FCOI:

- The name of the investigator with the FCOI
- The name of the entity with which the investigator has an FCOI
- The nature of the Significant Financial Interest (SFI)
- The value of the financial interest
- Description of how the financial interest relates to the NIH-funded research and why the institution determined that the financial interest conflicts with such research
- Description of the key elements of the institution's management plan, including other required information


Submitting an FCOI Report

Report FCOIs for grants and cooperative agreements through the eRA Commons FCOI Module. For contracts, contact the NIH Contracting Officer identified on the contract.

Learn how to submit a grant-related FCOI report through eRA Commons:

- [About the FCOI module](#)
- [Who Can Access the FCOI Module?](#)
- [Initiating an FCOI Report](#)
- [Submitting FCOI Report to Agency](#)
- [Searching Existing FCOI Reports \(Notifications\)](#)
- [Revising a Submitted FCOI Report \(Following a Retrospective Review Only\)](#)
- [Agency Requests for Additional Information](#)
- [FCOI History](#)
- [Submitting FCOI Annual Reports](#)
- [When Will I Receive a Notification?](#)

eRA FCOI module information:

- [eRA Commons FCOI module information page](#) 
- [Types of FCOI Reports Summary Chart](#) – (8/21/2012) – (MS Word) - Summary of different FCOI reports that can be submitted in the eRA Commons FCOI Module

Resources

- [Related NIH Guide Notices](#)
- [FCOI Policy Development Checklist 4/24/2020](#) (PDF) - An overview of the FCOI regulation to serve as a resource when developing, revising or reviewing an Institution's FCOI policy to determine compliance with all regulatory requirements. [[MS Word version](#) - 37 KB].
- [Instructions for submitting an FCOI Policy into eRA Commons IPF Module](#) (10/1/2020) – (PDF) – Instructions for submitting the institution's FCOI policy in the eRA Commons Institutional Profile (IPF) Module per NIH Guide Notice NOT-OD-21-002.
- [FCOI Noncompliance Reporting Requirements Summary Chart](#) – (8/21/2012) - (MS Word) - Summary of the reporting requirements when there is an instance of noncompliance with the FCOI regulation
- See also the [FCOI training](#) page.