



THE AGA KHAN UNIVERSITY

## **Guidelines concerning National Institutes of Health (NIH) Financial Conflict of Interest (FCOI) Policy**

### **1. Abbreviations**

NIH	:	National Institutes of Health
AKU	:	Aga Khan University
PHS	:	Public Health Service
COI	:	Conflict of Interest
FCOI	:	Financial Conflict of Interest
PI	:	Principal Investigator
Co-Is	:	Co-Investigator
FAQ	:	Frequently Asked Questions
SFI	:	Significant Financial Interest
HEI	:	Higher Education Institute
RO	:	Research Office, AKU

*“Capitalized terms used herein but not otherwise defined herein shall have the meanings provided to such terms in the FCOI Regulation.”*

### **2. Overview**

This document serves as a guideline and summarizes NIH’s FCOI requirements for all AKU Entities applying for, or in receipt of, funding through NIH contracts, grants or cooperative agreements and any other US Federally funded, contracts, grants and cooperative agreements. The full policy and associated detailed guidance (including FAQs) is available on the NIH website:

- [NIH Financial Conflict of Interest Policy](#)
- [NIH FCOI FAQs](#)

All departments/entities in receipt of NIH funding are required to demonstrate compliance with the NIH FCOI. The policy applies to funding awarded directly to AKU by NIH itself or its Institutes or indirectly, where AKU is (or receives funding from) a sub-awardee or sub-contractor.

### 3. Purpose of the FCOI Regulation

In consistent with NIH Grant Policy Statement [42 CFR 50.601](#), the FCOI regulation is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator FCOIs. The NIH is committed to safeguarding the public's trust in Federally-supported research that is conducted with the highest scientific and ethical standards.

The policy implies that:

1. The Institution is responsible for complying with the regulations, including maintaining a written and enforced FCOI policy; managing, reducing, or eliminating identified conflicts; and reporting identified conflicts to the PHS Awarding Component.
2. Investigators are responsible for complying with their Institution's written FCOI policy and for disclosing their SFIs to the Institution.

'Investigator' means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding, which may include, for example, collaborators or consultants.

### 4. Definition of a Financial Conflict of Interest

NIH defines that a financial conflict of interest exists when the University reasonably determines that an Investigator has a Significant Financial Interest ('SFI') that is related to a NIH-funded research project and that could directly and significantly affect the design, conduct or reporting of the NIH-funded research. SFIs that do not directly and significantly affect the design, conduct or reporting of the NIH-funded research do not fall under FCOIs.

**Significant Financial Interest** defined by NIH as:

- 4.1. A financial interest consisting of one or more of the following interests of an Investigator (and those of an Investigator's spouse and dependent children), that reasonably appears to be related to the Investigator's University responsibilities (these may include activities such as research, research consultation, teaching, professional practice, University committee memberships, and service on review board panels, etc.):
  - For any publicly traded Entity<sup>1</sup>, an SFI exists if the value of any remuneration (including salary and any payment for services not otherwise identified as salary, e.g. consulting fees, honoraria, paid authorship) received from the Entity in the 12 months

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<sup>1</sup> refers to any domestic or foreign, public or private organization (excluding a US Federal/government agency) from which an Investigator (and spouse and dependent children), receives remuneration or in which any person has an ownership or equity interest.

preceding the disclosure and the value of any equity interest (including any stock, stock option or other ownership interest as determined through reference to public prices) in the Entity as of the date of disclosure, when aggregated, exceeds US\$ 5,000.

- For any non-publicly traded Entity, an SFI exists if the value of any remuneration received from the Entity in the 12 months preceding the disclosure, when aggregated, exceeds US\$ 5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest.
- Intellectual property rights and interest (e.g. patents, copyrights) on receipt of income related to such rights and interest.

4.2. As SFIs, Investigators must also disclose the occurrence of any travel related to University responsibilities that is reimbursed or sponsored by commercial funders. This includes travel paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available. This does not include travel which an Investigator claims through the University's system for claiming expenses and is charged to a research project.

4.3. SFI **does not** include the following types of financial interests:

- i. Salary, royalties or other remuneration paid by the University to the Investigator if the Investigator is currently employed/appointed by the University.
- ii. Income from investment vehicles such as mutual funds and retirement accounts as long as the Investigator does not directly control the investment decisions made in these vehicles.
- iii. Income from seminars, lectures or teaching engagement sponsored by government, local government agency, HEI, academic teaching hospital, medical centre, research institute associated/affiliated with a HEI.
- iv. Income from service on advisory committees or review panels for a government, local government agency, HEI, academic teaching hospital, medical centre, research institute associated with a HEI.

## 5. Investigators' Responsibilities:

Under the NIH Financial Conflict of Interest Policy, Investigators are responsible for:

5.1. **Compulsory completion of the [NIH FCOI Training Module](#).** Investigators must complete the online NIH FCOI tutorial prior to engaging in research related to any NIH grant and at least every four (4) years. In addition, Investigators must repeat training when:

- 5.1.1. FCOI policy changes affect the requirements of the Investigator
- 5.1.2. The Investigator is new to AKU
- 5.1.3. When the Department/Entity finds an Investigator non-compliant with FCOI policy on NIH-funded projects or management plan.

**5.2. Disclosure of any Significant Financial Interest (SFI).** The time frames for disclosure of SFIs are:

5.2.1. No later than at the time of application for the NIH-funded research

5.2.2. At least annually during the period of the award

5.2.3. Within 30 days of discovering or acquiring a new SFI

Failure to disclose as per the timelines above will result in additional reporting obligations to the NIH.

**5.3. Adherence to the agreed Management Plan** (in the case of an identified FCOI)

5.3.1. Non-compliance to the management plan must be reported to the NIH.

**5.4. Disclosure of any FCOIs** in each public presentation of the results of a project (and as an addendum to previously published presentations) for any FCOI not properly managed or reported by the Investigator for a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment.

**5.5. Disclosure of commercially reimbursed or sponsored travel:** a requirement for any such travel (where the monetary value may not be readily available) related to the Investigator's responsibilities to be disclosed.

**5.6. Receive disclosures of Significant Financial Interest of Investigators at other institutions,** where AKU has or will subcontract institutions whose staff are to perform part of the project, and forward this to their Departmental / Divisional / Institute Manager (if not directly sent).

**5.7. Address and Monitoring sub-recipient compliance:** Via a written agreement ensure that the sub-recipient will follow the NIH FCOI policy and these guidelines of AKU and any Management Plans

Department / Entity Heads with clerical support from the administrator in the PI's department, are responsible for obtaining all Investigators' initial, on-going and annual SFI declarations and for forwarding details of declared SFIs to their department/entity heads to determine whether they constitute an FCOI due to (i) the impact on the NIH-funded project or (ii) the outcome the NIH-funded project may have on the SFI.

Where there are Investigators in different Departments/entities involved in the same NIH project, the administrator in the PI's Department/Entity is responsible for obtaining all Investigators' annual SFI declarations for that project and for promptly forwarding details of declared SFIs to the department/entity head of the PI's and relevant Co-I's Department/Entity for them to jointly determine any FCOI.

## **6. Department heads / Entity heads responsibilities:**

Under the NIH FCOI Policy, Department / Entity heads are responsible for:

- 6.1. On receipt of SFI declarations forwarded by Manager/Administrator, Department/Entity head will be responsible for determining whether an SFI declaration constitutes an FCOI due to (i) the impact on the NIH-funded project or (ii) the outcome the NIH-funded project may have on the SFI.

Where an FCOI has been declared for an Investigator in a different Department/Entity to the PI's Department/Entity, the Heads of both Department/Entity are to jointly determine any FCOI and work on the development of the Management Plan, where appropriate.

- 6.2. Where it is determined that an SFI constitutes an FCOI, the department/entity head will instruct the local administrator to communicate details to the Research Office, which will include reporting to the NIH and working with the Investigator and department/entity heads to develop and implement management plans to ensure that the FCOI is appropriately dealt with and controlled within the NIH specified timescales; this includes the completion of a formal Management Plan which is required to be submitted to the NIH.
- 6.3. Carry out a retrospective review when the Investigator fails to disclose any existing SFI, or the Investigator fails to comply with the FCOI Management Plan.
- 6.4. The department/entity head will be responsible for monitoring Investigator compliance with Management Plans until completion of the project.
- 6.5. In the event that a bias is identified in the design, conduct or reporting of a project, the department/entity heads in consultation with Research Office will promptly notify the NIH, complete a Mitigation Report and take such other necessary corrective actions.
- 6.6. In the event that an Investigator fails to comply with his/her obligations to the NIH and AKU with regards to any FCOI, including following an agreed management plan, the department/entity head and Research Office will promptly notify the NIH and take necessary corrective actions.
- 6.7. In the case of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment, corrective actions will include Investigators being required to disclose FCOIs in public presentations of the results of the project.

## 7. Research Office responsibilities:

In support of the above, the Research Office (RO) is responsible for:

- 7.1. **Initial FCOI disclosure:** At the time of new NIH applications, PI must submit ‘NIH Pre-Submission Declaration Form’ for Investigators to confirm their completion of the NIH tutorial and disclosure of SFIs. The form is required to be signed by all Investigators and relevant department/entity heads prior to RO approving the submission of an application to the NIH.
- 7.2. **Annual FCOI Report:** The RO will submit annual FCOI report linked to any FCOI previously reported. The Investigator / Department administrator/head must provide the following information to the RO;
  - Status of financial interests
  - Any changes in the management plan

Based on this information, the RO will submit a report to NIH through eRA Commons portal.

Annual FCOI reports must be submitted at the same time as when the Principal Investigator is required to submit the annual progress report throughout the life of the project which includes any extension periods. The annual FCOI report is submitted separately through the eRA Commons FCOI module and is not submitted as part of the annual progress report.

- 7.3. **Reporting identified FCOI via the NIH eRA Commons FCOI module** ([guide available](#)): RO must receive the information regarding FCOI from PI/Department head / administrator to report it to NIH within the 60-day deadline or, where AKU is a sub-recipient, to the lead applicant within the deadline set by that lead applicant.
- 7.4. **Maintaining records of the Significant Financial Interest, FCOI forms:** All FCOI related records (including records relating to the review of FCOIs) will be stored for 3 years from the date of final expenditure report is submitted to the NIH.
- 7.5. **Public Accessibility:** Make these Guidelines publicly accessible and post the same on AKU’s web site and make available information concerning identified FCOIs held by senior/key personnel (as defined by the FCOI regulation), publicly accessible prior to the expenditure of funds.

## 8. Management of FCOI:

- 8.1. Prior to the AKU’s expenditure of any PHS research funds department/entity heads shall:
  - i. review all Investigator disclosures of significant financial interests;

- ii. determine whether any significant financial interests relate to PHS-funded research;
- iii. determine whether a financial conflict of interest exists;

8.2. In case of any SFI the department/entity heads will develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Copy of the management plan shall be submitted to Research Office records.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- 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;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);  
or
- Severance of relationships that create financial conflicts.

8.3. Whenever, in the course of an ongoing research project,

- an Investigator who is new to participating in the research project discloses a significant financial interest or
- an existing Investigator discloses a new significant financial interest to the University or
- University identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the University

the department/entity head or designated administrator/manager of the University shall, within sixty(60) days:

- review the disclosure of the significant financial interest;
- determine whether it is related to PHS-funded research;
- determine whether a financial conflict of interest exists; and,

if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, the University may determine that additional interim measures are necessary regarding the Investigator's

participation in the NIH-funded research project between the date of disclosure and the completion of the Institution's review.

- 8.4. In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the University to constitute a financial conflict of interest; failure by the University to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the University shall, within 120 days of the University's determination of noncompliance, complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
- 8.5. Based on the results of the retrospective review, if appropriate, the University shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the University is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

## **9. Submission of FCOI report through eRA Commons System:**

- 9.1. Submission of the report is done through the eRA Commons system by the lead institution. Only an institutional Signing Official (SO) submit or assign FCOI role to others within the institution.
- 9.2. Where AKU is leading a project, the RO will report FCOI declared by the subrecipient through the University and/or Investigator eRA Commons FCOI account.
- 9.3. Where AKU is a subrecipient, the Investigator submits the applicable SFI, FCOI forms to the lead institution. The lead institution submits the report to the eRA Commons.
- 9.4. A user guide to submit the FCOI reports through the eRA Commons system is available at this link: [http://era.nih.gov/files/fcoi\\_user\\_guide.pdf](http://era.nih.gov/files/fcoi_user_guide.pdf)

## **10. Failure to Comply with FCOI Policy**

Any failure to comply with FCOI policy may;

- be considered as Research Misconduct and handled through AKU's Policy on Research Misconduct.
- halt any expenditures of funds on awards and/or subaward supported by a PHS grantee (including NIH).

**11. Forms:**

- NIH pre-submission FCOI disclosure form
- NIH pre-submission FCOI disclosure form for sub-awardee
- NIH retrospective FCOI disclosure form
- NIH SFI disclosure form
- NIH FCOI Management plan