

Standard Operating Procedures for the implementation of the National Institutes of Health (NIH) Financial Conflict of Interest (FCOI) Policy

1. Purpose

The Aga Khan University (AKU) is implementing these Standard Operating Procedures (SOPs) [refer to Annexure A for the process flow] as an addendum to its [guidelines concerning the National Institutes of Health \(NIH\) Financial Conflict of Interest \(FCOI\) Policy](#), which are issued under the [Policy For Submitting Extramural Grant Applications \(ORGS/007-2021\)](#). The purpose of these SOPs is to ensure compliance with [NIH policy Statement 42 CFR 50.601](#).

2. Applicability

The NIH FCOI Policy and these procedures will apply to every Investigator currently at the application stage or already a recipient of a grant, cooperative agreement, or contract from the NIH.

3. Definitions

3.1 Financial Conflict of Interest (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.

3.2 Investigator

Principal Investigator (PI) or Project Director (PD) 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. The PI / PD is responsible for determining any other individuals who meet this definition.

3.3 Significant Financial Interest (SFI)

Anything of monetary value or potential monetary value held by an Investigator (or by the Investigator's spouse or dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities including activities such as research, research consultation, teaching, professional practice, University committee memberships, and service on review board panels, etc.

SFI includes the following:

- 3.3.1 Remuneration such as salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship). It also includes equity interests from companies and organizations outside the Investigator's current institution if the value within the past 12 months, as of the date of disclosure, exceeds \$5,000.
- 3.3.2 Royalties related to intellectual property rights paid by any source other than the Investigator's current institution.

- 3.3.3 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 the Investigator's institutional responsibilities when the past 12 months aggregated amount paid to the specific Investigator exceeds \$5,000 per entity. This does not include travel which an Investigator claims through the University's system for claiming expenses and is charged to a research project.

The following are excluded from the definition of SFI and are not required to be disclosed:

- 3.3.4 Salary, royalties, or other remuneration paid to the Investigator from the institution that currently employs the Investigator.
- 3.3.5 Income from investments in mutual funds or retirement accounts, as long as the Investigator does not make the investment decisions.
- 3.3.6 Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels, sponsored by a government, local government agency, higher education institution (HEI), academic teaching hospital, medical centre, or research institute associated with or affiliated with an HEI.

4. Responsibilities

- 4.1 ***Vice Provost, Research:*** Oversees the implementation of the NIH FCOI policy via the Research Office Directors in Pakistan and East Africa.
- 4.2 ***Investigators¹:*** Complete required FCOI training, disclose SFIs, and prepare a management plan.
- 4.3 ***Principal Investigator / Project Director:*** Signs off and oversees the implementation of the management plan for any Investigator working under them.
- 4.4 ***FCOI Review Committee:*** Reviews disclosures, determines the presence of FCOIs, and develops and monitors management plans **if required**.
- 4.5 ***FCOI Officer:*** Collects and reviews disclosures, assists the FCOI review committee if required, facilitates training, maintains records, and assesses compliance.
- 4.6 ***Entity or Department Head / Immediate Supervisor:*** Ensures that Investigators complete the training and implement the management plans, as required.

5. Training Requirements

- 5.1 Each Investigator who plans to participate in, or is currently participating in, NIH-funded research must complete the FCOI training, regardless of whether an FCOI exists.
- 5.2 After completing the [NIH online tutorial](#), the Investigator must provide an electronic copy to the FCOI official in the AKU Global Research Office. The certificate should also be attached to the [Pure Award Management Module \(Pure AMM\)](#) in the respective grant application or award package.

¹ Investigators include PIs, PDs and any other person regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NIH.

5.3 Renewal of the training will be required:

- 5.3.1 At least every four years.
- 5.3.2 Whenever this procedure is revised in a way that affects Investigator requirements.
- 5.3.3 When an Investigator is new to the University and is receiving or plans to receive, NIH funds, unless the Investigator provides proof of valid training from a previous institution.
- 5.3.4 When the University determines that an Investigator is not in compliance with this procedure or a specific FCOI management plan.

5.4 If support is required for completing the training, the Investigator is to seek assistance from the FCOI Officer.

6. Disclosure requirement of SFI

- 6.1 Each Investigator who plans to participate in, or is participating in, NIH-funded research must disclose SFIs and those of their spouse/common-law partner and dependent children.
- 6.2 Investigators must complete the AKU [SFI Disclosure Form](#) which includes a management plan and submit it to the FCOI Officer during the pre-award phase. Investigators must confirm the accuracy of the disclosed information at the post-award stage, before the expenditure of any NIH-awarded funds. If updates are necessary, the AKU SFI Disclosure Form must be revised.
- 6.3 All Disclosure forms must be submitted to the FCOI Officer via this [online form](#).
- 6.4 Investigators must submit the AKU SFI Disclosure Form:
 - 6.4.1 At the time of NIH funding application submission.
 - 6.4.2 Annually during the award period.
 - 6.4.3 Within 30 days of a new SFI arising during the NIH project or a substantive change to an existing SFI.
 - 6.4.4 Within 30 days of new Investigators joining the project
- 6.5 Investigators must disclose financial interests and activities from the preceding 12 months or anticipated in the next 12 months.
- 6.6 In addition to SFI disclosures, Investigators must comply with the AKU's [Conflict of Interest Policy](#), which includes both financial and non-financial personal and institutional conflicts that could affect research integrity.

7. Review of SFI Disclosure Forms and Determination of an FCoI

- 7.1 The FCOI Officer will conduct an initial review of the SFI Disclosure Form and any associated separate management plan for each SFI to ensure its completeness and will gather any additional information, if necessary.
- 7.2 The FCOI Officer will review and assess disclosure forms at the following times:
 - 7.2.1 Before the University releases any funds for a research project funded by a funding source.
 - 7.2.2 Within 60 days during an ongoing funded project, under the following conditions:
 - a) A new Investigator joins the project and discloses an SFI.

- b) An existing Investigator discloses a new SFI or a substantive change to an existing SFI.
- 7.2.3 Within 60 days whenever the University identifies an SFI that was not:
 - a) Disclosed promptly by the Investigator.
 - b) Previously reviewed by the University during an ongoing funded research project.
- 7.3 During the screening review, the FCOI Officer will assess the disclosure and exclude the following cases from further review:
 - 7.3.1 If the Investigator has reported no financial interests to disclose.
 - 7.3.2 If the disclosed financial interests do not meet the thresholds set by the SFI criteria.
- 7.4 The FCOI Officer will review and escalate disclosures that meet or exceed the thresholds as per the definition of an [SFI](#).
- 7.5 The FCOI Officer will determine a financial conflict of interest based on:
 - 7.5.1 The determination of relatedness to the research.
 - 7.5.2 Potential impact on the conduct of the study.
 - 7.5.3 The degree of risk associated with the situation including, but not limited to:
 - a) Potential risks to human research subjects (e.g., due to participation in research in which the results are subsequently invalidated due to the possibility of bias).
 - b) Reputational/career risks to the Investigator.
 - c) Reputational/financial risks to the institution.
 - 7.5.4 Possibility of financial benefit to the researcher.
 - 7.5.5 Possibility of benefit to the outside entity.
 - 7.5.6 Whether the conflict could be managed appropriately without a change in PI.

8. FCOI Review Committee

- 8.1 The FCOI Review Committee consists of the Director, Research PK/ EA (as the case may be by region), Associate Dean, Research PK/EA (as the case may be by region), a nominee from the Legal Office (PK/EA), an Ethics Review Committee (ERC) member (as needed) an external member and the FCOI Officer as the secretary.
- 8.2 The FCOI Officer will convene a meeting of the FCOI Review Committee, through the RO for final determination and management of the FCOI, **when and if needed**.

9. Management plans for Identified FCOI

- 9.1 When the FCOI Officer determines the Investigator has a financial conflict of interest, a management plan prepared by the Investigator is reviewed to address the financial conflict of interest.
- 9.2 The FCOI Officer will work with the Investigator to ensure an appropriate /elaborate management plan is prepared for SFI (as required by the [NIH checklist](#)) with the reasonable expectation that NIH-funded research associated with the Investigator's FCOI will be free from bias.

- 9.3 The actions required under the management plan may vary depending on the nature and extent of the FCOI and the nature of the NIH-funded research.
- 9.4 Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate an Investigator's FCOI include, but are not limited to:
 - 9.4.1 Public disclosure of the FCOI.
 - 9.4.2 For research projects involving human subjects, disclosure of the FCOI to the participants.
 - 9.4.3 Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research against bias resulting from the FCOI.
 - 9.4.4 Modification of the research plan or research activities.
 - 9.4.5 Requiring a change in personnel and/or responsibilities for all or a portion of the research activities, including the informed consent process for human subjects involved in the research.
 - 9.4.6 Double-blind data analysis.
 - 9.4.7 Data analysis and interpretation by independent reviewers or review of raw data and manuscript by an external independent reviewer.
 - 9.4.8 Disqualification of personnel from participation in that portion of the research activities that would be affected by the FCOI.
 - 9.4.9 Reduction or elimination of the financial interest (e.g., sale of an equity interest).
 - 9.4.10 Severance of relationships that create an FCOI.
- 9.5 The FCOI Officer will convene a meeting of the FCOI Review Committee, through the RO for final determination and management of the FCOI, **when and if needed**.
- 9.6 The FCOI Officer also communicates the management plan to the PI/PD and/or the Immediate Supervisor (if the PI/PD is the same person) for implementation.
- 9.7 The Immediate Supervisor is responsible for ensuring the management plan is implemented at the departmental level throughout the NIH project.
- 9.8 The FCOI Officer ensures that an identified FCOI is managed within 60 days of disclosure or discovery.
- 9.9 The FCOI Officer monitors² the Investigator's compliance with the management plan until the project's completion.

10. Retrospective Review, and Mitigation Plans

- 10.1 If a compliance failure is identified in NIH-funded research, a retrospective review will be conducted in the following cases:
 - 10.1.1 Delay/failure to disclose an SFI that constitutes an FCOI.
 - 10.1.2 Failure to comply with the FCOI management plan.
- 10.2 The retrospective review will be completed within 120 days of determining non-compliance and assessing whether NIH-funded research was biased in design, conduct, or reporting.
- 10.3 The FCOI Officer will conduct and document the retrospective review, including key elements such as project details, methodology, findings, and conclusions.

² The monitoring of management plan will be conducted through ongoing reviews by (i) Ethical and Review Board (ERB) and (ii) Compliance reviews.

- 10.4 The FCOI Officer will determine any necessary corrective actions or sanctions. Based on the retrospective review, the FCOI report will be updated as needed with actions to manage the FCOI moving forward.
- 10.5 If bias is found, the FCOI Officer will notify the NIH promptly and submit a mitigation report, including the impact of bias and corrective actions. The FCOI Officer will continue to submit annual FCOI reports, as required.

11. Reporting requirements to NIH

- 11.1 If an FCOI is determined to exist on NIH-supported research, an FCOI report will be submitted to NIH. The report is submitted through the eRA Commons system by the FCOI Officer as per the following requirements and timelines. FCOIs related to intellectual property developed at AKU do not need to be reported to NIH.

Reports	Content	Timelines
Initial	Project number, Project title, Name of PI, Name of Investigator with FCOI, Name of entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key elements of management plan.	<ol style="list-style-type: none"> 1. Prior to expenditure of Funds. 2. Within 60 days of: <ol style="list-style-type: none"> a) Identification of FCOI for an Investigator who is newly participating in the project. b) New, or newly identified, FCOIs for existing Investigators.
Annual	Status of FCOI and changes to the management plan (if applicable), until the completion of the project.	An annual report is due at the same time as when submitting the annual progress report or at the time of extension.
Revised	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward.	After completion of retrospective review, if needed.
Mitigation	Project number, Project title, Name of PI, Name of Investigator with FCOI, Name of entity with FCOI, Reason for review, Detailed methodology, Findings and conclusion.	When a bias is found because of a retrospective review.

- 11.2 A user guide to submit the FCOI reports through the NIH eRA Commons system is available at this link: https://www.era.nih.gov/files/fcoi_user_guide.pdf

12. Record Keeping

- 12.1 The FCOI Officer from RO will maintain records of training certificates, disclosures, reviews management plans and minutes of FCOI Review Committee meetings (if any) for a minimum of three years after the life cycle of the grant.
- 12.2 Information concerning the FCOI will remain available for responses to written requests for at least three (3) years from the date that the information was most recently updated.

13. Subrecipient Requirements

- 13.1.1 The PI shall be responsible for ensuring that the written agreement must include whether the subrecipient will follow the FCOI guidelines of AKU or FCOI policy of their own institution.
- 13.1.2 If the subrecipient has their own FCOI policy/procedures ensuring complying with NIH policy, then the PI is required to obtain a certification from the subrecipient.

- 13.1.3 Alternatively, if the subrecipient does not have their own FCOI policy/procedures, then the PI is required to have it mentioned in an agreement that the subrecipient will comply with AKU's FCOI NIH guidelines.
- 13.1.4 For subrecipients relying on AKU's FCOI policy/procedures, the PI is to obtain/submit all subrecipient disclosure forms to FCOI Officer within 30 days prior to initiation of project that allows FCOI Officer to identify, determine, manage, and report FCOI to NIH as required by regulation.
- 13.1.5 Simultaneously, for subrecipients relying on AKU's FCOI policy/procedures, the PI must obtain all subrecipient Investigator's training certificates prior to engaging in research activities. The certificates must be submitted to the FCOI Officer.

14. Public Disclosure

- 14.1 All information requests pertaining to the determined FCOI must be sent to the FCOI Officer via email at research.compliance@aku.edu (with a cc to nbi.grantssupportEA@aku.edu for cases that pertain to EA), who will respond within five business days of receipt of the request.
- 14.2 The FCOI Officer will provide information as per applicable regulation and law such as the Investigator's title and role; entity's name; nature of the SFI; approximate dollar value of the SFI and/or a statement where value cannot be readily determined based on fair market value.
- 14.3 Information concerning the FCOI will remain available for responses to written requests for at least three (3) years from the date the final expenditures report for the related project was submitted to NIH.

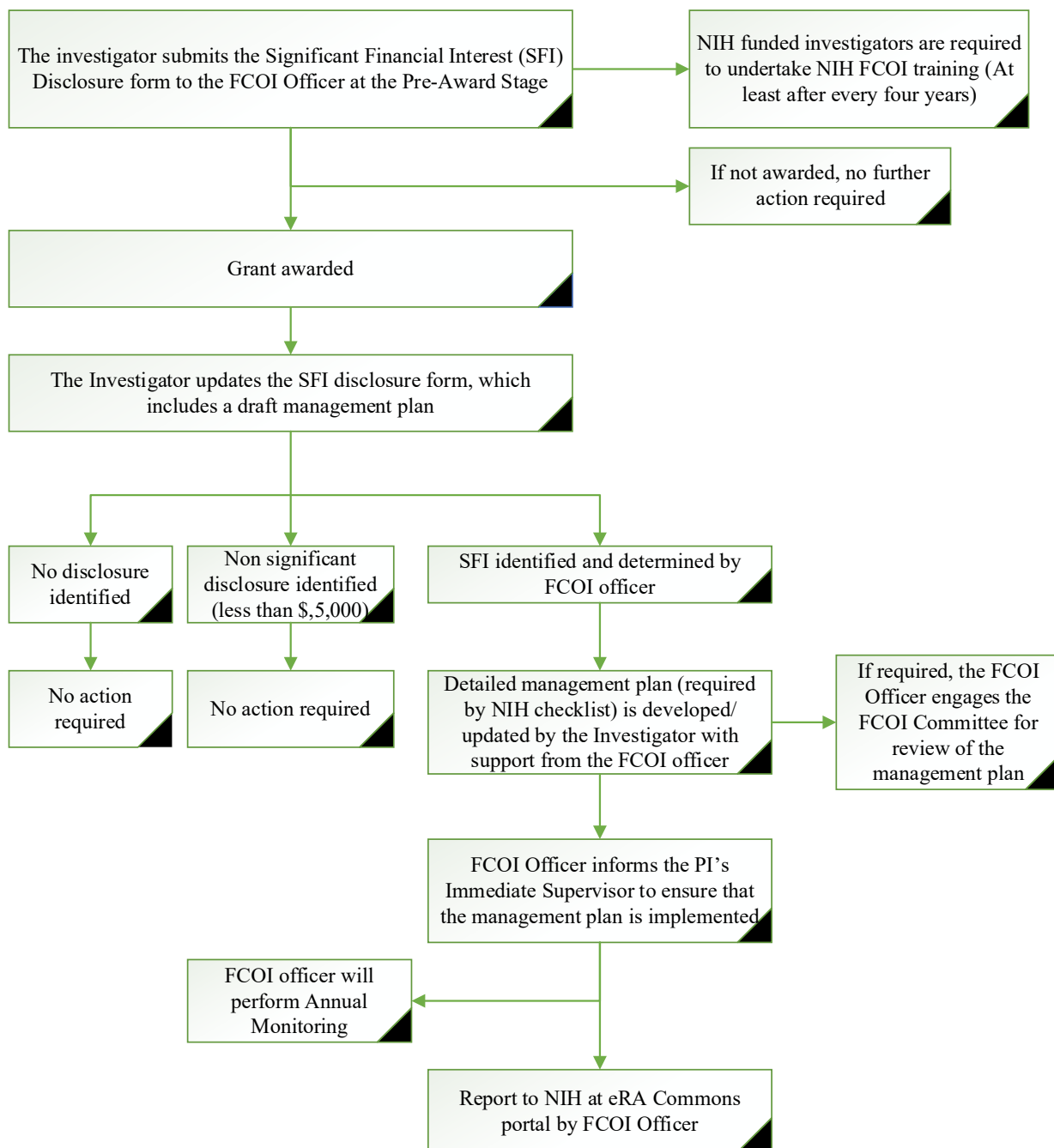
15. Review and Revisions

- 15.1 These SOPs will be reviewed/updated as per the institutional requirement and/or as and when required to ensure compliance with NIH regulations.

Dated: April 17, 2025

Annexure A

Financial Conflict of Interest (FCOI) Process Flow



Quick References:

- [NIH Policy Statement \(42 CFR 50.601\);](#)
- [Policy For Submitting Extramural Grant Applications \(ORGS/007-2021\);](#)
- [Guidelines concerning National Institutes of Health \(NIH\) Financial Conflict of Interest \(FCOI\) Policy;](#)