



## **Khon Kaen University Financial Conflict of Interest Policy**

### **For PHS/NIH Projects**

Khon Kaen University (KKU) has a responsibility to ensure that its teaching, academic services and research environment foster the generation of new knowledge and positive learning opportunities for students and preserves the integrity of its research enterprise and the public's trust. The Financial Conflict of Interest (FCOI) Policy, therefore, requires that all employees of Khon Kaen University ("University" or "KKU") such as faculty, researchers, lecturers and staff and others acting on its behalf avoid or mitigate real or perceived financial conflicts of interest and ensure that their activities do not conflict with their obligations to KKU or its welfare. The Vice President for Research and Graduate Studies is responsible for ensuring implementation of this Policy.

#### **1. Purpose**

The purpose of this Policy is to provide a framework disclosure of financial interests and other related actions during such interactions to ensure that members of KKU engage in research objectively with integrity and transparency, while being able to maintain acceptable relationships with outside entities and individuals.

This Policy is intended to be applied in conjunction with the values and code of ethics issued by the Ministry of Higher Education, Science, Research and Innovation of Thailand and KKU. Furthermore, as a recipient of funding from the federal government of the United States, this Policy also implements the FCOI regulations of the U. S. Public Health Service/National Institutes of Health (PHS/NIH) to comply with Regulations at [42 CFR Part 50 Subpart F](#). The NIH FCOI policy requires that the University identifies, discloses and manages the FCOI of grant recipients where we reasonably determine that an Investigator has a 'Significant Financial Interest' (SFI), related to an PHS/NIH-funded research project, that could affect the objectivity of PHS/NIH-funded research. In order to make this determination, Investigators must declare their SFIs to the University. Additionally, the PHS/NIH requires regular and compulsory PHS/NIH FCOI training for all Investigators and continuous disclosure and management of identified FCOIs.

#### **2. Applicability**

The requirements for **Investigators** set out in this Policy apply to any person identified as senior or key personnel in a PHS/NIH grant application or progress report who can directly or materially influence the research, or who is responsible for the design, conduct and reporting of such research, whether the University is a Prime Awardee or a Sub-awardee.

The University's first named Investigator (**Principal Investigator**) has additional responsibilities. The Vice President for Research and Graduate Studies acts as the University's **Institutional Official** to determine whether an FCOI exists and to implement and monitor management plans.

### 3. Responsibilities

#### 3.1 Investigators

- (a) Must undertake FCOI training on the Investigator's responsibilities regarding disclosure of SFIs, available through the [NIH FCOI Online Tutorial](#), prior to commencing any PHS/NIH funded research at the University and at least every four years, and immediately under the designated circumstances (See Section below on Training requirements);
- (b) Disclose any and all identified SFIs (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities using the University's SFI Disclosure Form (available upon request from the Office of Research and Graduate Studies) and submit to the Institutional Official:
  - (i) No later than at the time of application for PHS/NIH funding;
  - (ii) At least annually during the grant period in conjunction with filing the required annual report;
  - (iii) within **30 days** of acquiring or discovering a new SFIs.
- (c) Assist with the development of a management plan for any identified SFIs determined by the University to directly and significantly affect the design, conduct or reporting of the PHS/NIH project (FCOI);
- (d) Comply with this Policy and with any management plan developed to manage any identified FCOIs;
- (e) Assist with completing any reports that are required to be provided to the PHS/NIH by the University; and
- (f) Comply with any other obligations under the NIH policy.

#### 3.2 Principal Investigator

- (a) The Principal Investigator is the University's first named investigator on the PHS/NIH grant.
- (b) The Principal Investigator must comply with all Investigator Responsibilities and, in addition, ensure that all University Investigators involved in the PHS/NIH project are aware of, comply with and make any disclosures required under this Policy, including completing the SFI Disclosure Form for any SFIs identified in the FCOI Screening Form.

#### 3.3 Institutional Official

- (a) Review disclosures of Significant Financial Interests and determine if a FCOI exists (refer to Determination of FCOI below);
- (b) Manage FCOIs, including through the development and implementation of management plans and monitoring compliance (refer to Management Plans), with Institutional oversight/escalation to KKU Research Integrity Committee;

- (c) Maintain records relating to all Investigator disclosures of financial interests and review of and actions taken related to such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for **at least three years** from the date of the final expenditures report is submitted to NIH, or, where applicable, from other dates specified in 45 CFR 75.361 for different situations; and
- (d) Comply with any other obligations under the NIH policy.

### 3.4 Office of Research and Graduate Studies

- (a) Inform each investigator the University's FCOI Policy, the Investigator's responsibilities regarding disclosure of SFIs, and related U.S. Federal regulations.
- (b) Provide annual and ad hoc FCOI reports to PHS/NIH via the eRA Commons FCOI Module;
- (c) Maintain central records relating to all Investigator disclosures of financial interests and review of and actions taken related to such disclosures for **at least three years** from the date of the final expenditures report is submitted to NIH, or, where applicable, from other dates specified in 45 CFR 75.361;
- (d) Address non-compliance in accordance with this Policy;
- (e) Take relevant corrective actions;
- (f) Receive, review and register changes to FCOIs;
- (g) Develop and implement Institutional-level processes to comply with PHS/NIH policy;
- (h) Report to NIH within **60 days** of changes to FCOIs arising;
- (i) Provide Institutional-level monitoring and assurance; and
- (j) Record completion of training by all Investigators.

## 4. Training Requirements

4.1 Each Investigator must understand their responsibilities under this Policy and the NIH policy, and must complete the NIH's Financial Conflict of Interest Training Module, available at: [https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html):

- (a) prior to engaging in PHS/NIH-funded research;
- (b) at least once **every 4 years**; and
- (c) immediately when any of the following circumstances apply:
  - (i) this Policy or procedures relating to FCOI policies are revised in any manner that affects the requirements of Investigators;
  - (ii) an Investigator is new to the University, even if the PHS/NIH-funded research has already begun; or
  - (iii) an Investigator is not in compliance with this Policy or a management plan, as determined by the Institutional Official.

4.2 When the NIH online tutorial has been completed, the Investigator must save an electronic copy of the certificate generated through the system and provide a copy to the Office of Research and Graduate Studies.

## **5. Definition of Significant financial interest (SFI)**

5.1 A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- (a) With regard to any publicly traded entity, a SFI 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 US\$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); 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;
- (b) With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve 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 (e.g., stock, stock option, or other ownership interest); or
- (c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income exceeding US\$5,000 related to such rights and interests.
- (d) Reimbursed or sponsored travel undertaken by the Investigator and related to = his/her institutional responsibilities over the past twelve months, which exceeds US\$5,000 per entity. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available.

5.2 The term SFI does not include the following types of financial interests:

- (a) salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
- (b) 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;
- (c) income from seminars, lectures, or teaching engagements sponsored by a U.S. 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 center, or a research institute that is affiliated with an institution of higher education; or
- (d) income from service on advisory committees or review panels for a U.S. 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 center, or a research institute that is affiliated with an institution of higher education.

- (e) travel that is reimbursed or sponsored by a U.S. 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 center, or a research institute that is affiliated with an Institution of higher education

## 6. Determination of FCOI

- 6.1 The Institutional Official (Vice-President for Research and Graduate Studies) determines, on behalf of the University, whether an FCOI exists for the purposes of the FCOI regulation.
- 6.2 The Institutional Official must determine whether the SFI declared by the Investigator may reasonably be said to be related to the PHS/NIH research by assessing whether the SFI:
  - (a) could be affected by the PHS/NIH research; or
  - (b) is in an entity whose financial interest could be affected by the PHS/NIH research.
- 6.3 If the SFI is determined by the Institutional Official to be related to the PHS/NIH research, the Institutional Official must determine whether the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH research.
- 6.4 If the SFI is determined by the Institutional Official to both:
  - (a) relate to the NIH research; and
  - (b) affect the design, conduct or reporting of the PHS/NIH research, it is an FCOI, and must be managed (see below).
- 6.5 Advice can be sought from the KKU Research Integrity Committee.

## 7. Management Plans

- 7.1 Where a FCOI is identified, the Institutional Official must **within 60 days** of the FCOI being identified develop and implement a management plan that specifies the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
  - (a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to staff members working on the project; to the KKU Ethics Committee in Human Research, Animal Ethics Committee, etc.);
  - (b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
  - (c) 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;
  - (d) Modification of the research plan;
  - (e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - (f) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
  - (g) Severance of relationships that create financial conflicts.
- 7.2 The Institutional Official must appropriately monitor compliance at the local level with any management plan until the completion of the PHS/NIH project.

## 8. Non-compliance and Remedies

- 8.1 In the event that an incidence of non-compliance or suspected non-compliance is identified, Investigators and Institutional Officials must immediately:
- (a) report the non-compliance or suspected non-compliance to the KKU Research Integrity Committee; and
  - (b) take all necessary steps to retrospectively comply with this Policy relating to disclosure, determination and management of SFIs.
- 8.2 If the Institutional Official determines that a FCOI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a SFI that is determined to be a FCOI, failure by the University to review or manage such a FCOI, or failure by an Investigator to materially comply with a management plan for a FCOI, within **120 days**, the KKU Research Integrity Committee will complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.
- 8.3 Documentation of the retrospective review shall include at least the following key elements:
- (a) Project number;
  - (b) Project title;
  - (c) PI or contact PI if a multiple PI model is used;
  - (d) Name of the Investigator with the FCOI;
  - (e) Name of the entity with which the Investigator has an FCOI;
  - (f) Reason(s) for the retrospective review;
  - (g) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
  - (h) Findings of the review; and
  - (i) Conclusions of the review.
- 8.4 Where non-compliance relates to PHS/ NIH clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the University may require the Investigators to disclose the FCOI in each public presentation and request an addendum to previously published outcomes relating to the research, and the Investigators must comply with this requirement.
- 8.5 In the event of non-compliance with any requirements under this Policy, the University may take corrective actions in accordance with applicable University and NIH policies and procedures, including withholding access to NIH funds and/or suspending project activity.

## 9. Maintenance of Records

- 9.1 Principal Investigators, Investigators and Institutional Officials must create, maintain and store all records relating to implementation of this Policy for **at least 3 years** following the submission of the final expenditures report to the NIH (or such other period as specified in 45 CFR 75.361 for different situations), and in accordance with the University's record-keeping policies. In addition, the University will store and retain all relevant central records, including disclosure forms and conflict management plans, and related documents, in accordance with NIH and University requirements.

## 10. Requirements regarding Subrecipients

- 10.1 If the University is the prime awardee, the University delegates responsibility for compliance with the NIH FCOI policy relating to identification, disclosure, determination and management of FCOIs to each sub-awardee, and will specify in any sub-awardee agreement all matters necessary to implement 42 CFR 50.604, including that the sub-awardee must:
- (a) comply with the requirements of the NIH FCOI policy;
  - (b) submit all requisite details of FCOIs to the University:
    - (i) prior to the expenditure of funds; and
    - (ii) within **60 days** of any subsequently identified FCOI;
  - (c) promptly notify the University of any management plan and suspected non-compliance; and
  - (d) provide a declaration that all FCOIs have been identified, disclosed and managed in accordance with NIH requirements.

## 11. Public accessibility requirements

- 11.1 This Policy must be published on the University's publicly accessible website.
- 11.2 The University will, within **5 business days** of a request, disclose requisite details of any FCOIs upon written request. The information shall include at least the following:
- (a) Investigator's name;
  - (b) Investigator's title and role with respect to the research project;
  - (c) Name of the entity in which the SFI is held;
  - (d) Nature of the SFI; and
  - (e) Approximate dollar value of the SFI (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.