



## **Prince of Songkla University Financial Conflict of Interest Policy**

### **1. Policy Statement**

This Financial Conflict of Interest (FCOI) Policy shall apply to all employees of Prince of Songkla University ("University" or "PSU") who conduct or collaborate on grants, research or projects in the role of an Investigator. It is designed to avoid all manners of FCOI and to provide a process by which the University will manage, administer, reduce or eliminate those conflicts.

### **2. Purpose**

In accordance with mission of Prince of Songkla University to build academic leadership through research, the University recognizes that research objectivity and integrity are of paramount importance and form the basis for obtaining and maintaining the public's trust. When PSU's faculty, students, and staff interact with outside entities and individuals in their capacity as members of the PSU community, there is potential for FCOIs. As such, PSU is responsible for identifying and managing FCOIs of an Investigator's personal financial interests (as well as those of the Investigator's closely-associated individuals). This process will help to strengthen accountability and transparency to promote objectivity in research. 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 the University engages 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 PSU. Furthermore, as a recipient of funding from the federal government of the United States ("U.S."), this Policy also implements the FCOI regulation of the U.S. Public Health Service Regulations at 42 C.F.R. Part 50.

### **3. Principles and Definitions**

- 1) *Closely-associated individuals* means any of the following persons or Entities deemed to be closely associated with a PSU Investigator in consideration of the existence of FCOI:
  - i. a spouse, child, de factor spouse, or close relation of the individual;

- ii. a superior or a subordinate staff member;
  - iii. a person with whom the individual has a current and ongoing professional relationship and from whom the individual receives fees or benefits for professional or other services;
  - iv. a business partner of the individual or a corporation in which the individual has financial or other personal interests;
  - v. a privately owned company of which the individual is a shareholder; and a beneficiary under a trust of which the individual is a trustee.
- 2) *Entity* means any domestic or foreign, public or private, for-profit or not for-profit, business, organization, or association from which an Investigator (or closely-associated individuals) receives remuneration or in which the Investigator (or closely-associated individuals) has an ownership or equity interest. This definition excludes Thai and US federal, state/provincial, and local government agencies.
- 3) *Financial Conflict of Interest (FCOI)* means any situation where a Significant Financial Interest could directly and significantly affect the planning, design, conduct, evaluation, or reporting of Research. In a research project, FCOI may occur when a staff member's responsibilities conflict with his/her private or personal interests. It raises questions of objectivity in research and/or improper gains. Most conflicts can be resolved completely without interfering research activity. However, a PSU Investigator may be deemed to have a FCOI if he/she or one or a closely-associated individual has an expectation of receiving a direct or indirect pecuniary and/or non-pecuniary benefit. In addition, the individual will be deemed to have a FCOI if he/she or his/her office suffers, or has a reasonable expectation of suffering, a pecuniary or non-pecuniary detriment to PSU.
- 4) *Financial Interest (FI)* means anything of monetary value (including but not limited to: income, honoraria, or other compensation including equity, stock or stock options, royalties or other distributions, the right to future royalties or other distributions, proprietary interests in intellectual property, or in-kind interests) received by an Investigator (or closely-associated individuals)
- 5) *Institution* means any domestic or foreign, public or private, entity or organization that is applying or receives research funding from funding agencies, including funding from the U.S. National Institute of Health.
- 6) *Institutional Official* means the individual within PSU who has been designed to solicit and review documents related to FCOI. For the purpose of this policy, the Institutional Official shall be the Vice President for Research and Innovation

- 7) *Institutional responsibilities* means an Investigator's professional responsibilities on behalf of PSU, including but not limited to: research, research consultation, teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- 8) *Investigator* means any individual, regardless of title or position, who is responsible for the design, conduct, or reporting of research under PSU. In this policy, the term "Investigator" does not include individuals who perform only incidental or isolated tasks related to a research project.
- 9) *Research* refers to a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. In this policy, the term "research" includes but is not limited to such activity for which funding is available from an Entity or the Thai and U.S. federal governments.
- 10) *Senior or Key personnel* means the project director or principal investigator (PD/PI) or any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to a relevant Entity or agency by law or regulation.
- 11) *Significant Financial Interest (SFI)* includes:
  - i. The value of Financial Interest received from any publicly or non-publicly traded entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure which, when aggregated, exceeds 200,000 Thai Baht
  - ii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests

#### **4. Policy**

The following FCOI policy and recommendations apply to all actions and decisions taken by a PSU employee in the name of or on behalf of the University:

##### **Disclosure of Financial Interest**

FI of PSU Investigators (and closely-associated individuals) must be identified, disclosed, and reviewed for potential institutional conflicts of interest. A PSU Investigator (or his/her closely-associated individual) who has a FI in an Entity and who is in a position to influence contracts between the University and an Entity must declare any potential COI and/or FCOI to his/her supervisor and/or the Office of Legal Affairs, PSU. All direct or indirect pecuniary interests and SFI must always be disclosed in advance of an application for sponsored funding as required by

this Policy and/or by a sponsoring agency (e.g., the U.S. Department of Health and Human Services, 42 C.F.R. Part 50.604(e)(1)).

### **Restrictions and Management of Financial Conflict of Interest**

Investigators are prohibited from attending meetings, offer opinions, or discuss matters in which the Investigator believes that he or she may have a COI or FCOI. Investigators who are unsure of their COI and/or FCOI status when taking actions or making decisions on behalf of PSU are required to seek clarification from their supervisor and/or Office of Legal Affairs, PSU. FI in the amount that meets the criteria for Significant Financial Interest (SFI) must be reported to the Research and Development Office (RDO), PSU, where an Institutional Official will solicit and review related documents and confirm whether an Investigator or his/her closely-associated individuals have SFI that creates a FCOI. The Institutional Official will then develop an FCOI Management Plan to which the Investigator must agree in writing.

### **Penalty for Non-compliance to the Policy**

Non-compliance with a duty imposed under this policy may be interpreted as misconduct. When an individual claims that he/she was unaware that he/she had a COI and/or FCOI, the burden of proof will rest with the individual and he/she will have to prove that he/she was not, at the material time, aware of his/her COI and/or FCOI.

## **5. Implementation**

### **Training**

Through normal communication channels, the University shall inform each Investigator of the Policy outlined in this document, the disclosure responsibilities of the Investigator, and related U.S. Federal Regulations for Investigators who wish to apply for funding from the U.S. federal government (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.604(b)).

Each investigator who applies for grants from the U.S. Public Health Service or the U.S. National Institute of Health, the University are required to complete FCOI training prior to engaging in the research, at least once every four (4) years. The training requirement shall be done immediately in cases that: 1) the University revises its FCOI policy that affects the requirements of Investigators, 2) the Investigator is newly appointed to the University, or 3) the Investigator is not in compliance with the Policy or management plan (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.604(b)).

### **Disclosure**

Investigators are required to disclose their SFIs (and those of their closely-associated individuals) related to the Investigator's institutional responsibilities prior to applying for research grants from a funding agency. For funding from the U.S. Public Health Service or the U.S. National Institute of Health, Investigators are also required to disclose their SFIs (and those of their closely-associated individuals) to the Institutional Official: 1) No later than at the time of

application for PHS-funded research, 2) annually during the period of the award, and 3) within thirty (30) days of discovering or acquiring a new SFI (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.603; 42 C.F.R. Part 50.604(e)(1)-(3)). The Institutional Official for the purpose of this policy shall be the Vice President for Research and Innovation, PSU.

### **Review Process**

The University shall provide adequate guidelines consistent with its regulations for the Institutional Official to review and determine whether an Investigator's SFI is related to the research and, if so related, whether the SFI is an FCOI. The Institutional Official shall solicit and review related documents and assess the FCOI status according to the mentioned guidelines. Generally, an SFI will be considered as being related to the funded research when the University, through the Institutional Official, reasonably determines that the SFI: 1) could be affected by the funded research; 2) is in an Entity whose financial interest could be affected by the research, or; 3) could directly and significantly affect the design, conduct, or reporting of the funded research. The Investigator may be involved in making the determination of whether the SFI is related to the funded research (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.604(f)).

Prior to Institution's expenditure of funds, the designated Institutional Official (Vice President for Research and Innovation) shall: 1) review all Investigators SFI disclosures; 2) determine if any SFI relates to PHS-funded research; 3) determine if an FCOI exists (SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research), and; 4) develop and implement management plans, as needed to manage FCOIs (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.605(a)(1)).

### **Monitoring**

When a new or existing Investigator in a research project discloses a new SFI, the Institutional Official shall review the SFI disclosure within sixty (60) days, determine whether the SFI is related to the Research, determine whether the SFI is considered to be an FCOI, and develop an FCOI Management Plan (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.605(a)(2)).

When the University identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the University during an ongoing research project, the Institutional Official shall review the SFI disclosure within sixty (60) days, determine whether the SFI is related to the Research, determine whether the SFI is considered to be an FCOI, and develop an FCOI Management Plan (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.605(a)(3) and (i)-(iii)).

### **FCOI Management Plan**

The Investigator must indicate that he/she agrees with the FCOI Management Plan in writing. The FCOI Management Plan may include conditions or restrictions imposed to manage such conflict of interest. Examples of conditions or restrictions in the FCOI Management Plan include but are not limited to the following:

- Full public disclosure of FCOI in reporting and publication of protocols and findings of the funded research, and full disclosure to all relevant stakeholders, including staff working on the project and the Institutional Review Board;
- Disclosure of FCOI directly to participants during the informed consent process for projects involving human subjects research
- Appointment of an independent monitor (or a monitoring committee) who is authorized to take measures to protect the design, conduct, and reporting of the research against FCOI;
- Modification of research plan;
- Change, restriction, or disqualification of personnel involved in parts of the project or the entire project;
- Reduction or elimination of the financial interest (e.g., sale or transfer of an equity interest or asset), or;
- Severance of relationships that create the FCOI

The mentioned conditions may be modified and additional conditions may be included in the FCOI Management Plan as deemed appropriate at the University's discretion (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.604(f); 42 C.F.R. Part 50.605(a)(1)). The actions in the Management Plan shall be taken and monitored for Investigator compliance until the completion of the research project (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.604(g); 42 C.F.R. Part 50.605(a)(4)).

### **Maintenance of Records**

The University shall maintain all FCOI-related records relating to all Investigator disclosures of financial interests and the University's review of and response to such disclosures and all actions under the University's policy or retrospective review (if applicable): 1) for a period of at least three (3) years from the date the final expenditure report is submitted to the funding agency, or; 2) from other dates specified in U.S. Department of Health and Human Services, 45 C.F.R. Part 75.361 for different situations (when applicable)

### **Enforcement Mechanisms and Remedies and Noncompliance**

A University employee who deliberately fail to comply with the measures outlined in this Policy document shall be considered as having committed disciplinary misconduct and subject to

administrative actions as outlined in Section 48 of the Regulation of PSU on Personnel Management of University Employees, B.E. 2559 (2016 A.D.), including:

- 1) Probation;
- 2) Pay cut;
- 3) Dismissal;
- 4) Expulsion.

Other administrative actions not outlined in the Regulation may be taken as deemed appropriate by the University. Administrative Actions shall be taken according to the normal chain of command of the University (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.604(i)).

In addition, when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, the University shall complete a retrospective review within 60 days, including but not limited to the following circumstances (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.605(a)(3)):

- Failure by the Investigator to disclose a significant financial interest that is determined by the University to constitute an FCOI;
- Failure by the University to review or manage such an FCOI;
- Failure by the Investigator to comply with the FCOI Management Plan.

The University shall document the retrospective review which shall include, at a minimum, the following key elements (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.605(a)(3)(ii)(B)):

- Project Number;
- Project Title;
- PD/PI or contact PD/PI if multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the Entity with which the Investigator has an FCOI;
- Reasons for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed);
- Findings of the review, and;
- Conclusions of the review.

For projects funded by the U.S. Department of Health and Human Services, in any case in which the U.S. Department of Health and Human Services determines that a research project funded by the U.S. Public Health Service / U.S. National Institute of Health to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the University as required

by the regulation, the University shall require the Investigator involved to take the following actions (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.606(c)):

- 1) Disclose the FCOI in each public presentation of the results of the research, and;
- 2) Request an addendum to previously-published presentations.

### **Subrecipient Requirements**

When the project has subrecipients (e.g., subcontractors or consortium members), the University will ensure that the subrecipient is compliant with the regulation and report identified financial conflicts of interests for subrecipient investigators to the funding agency. The University shall, where applicable, establish via a written agreement whether the subrecipient will follow the FCOI policy of the University or the subrecipient's own FCOI policy. Actions taken by the University may include, but not be limited to, the following (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.604(c); 42 C.F.R. Part 50.604(c)(1)(i)-(iii); NIH Grants Policy Statement 15.2.1):

- Obtain a certification from the subrecipient that its FCOI policy complies with the regulation (if applicable)
- Include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the University to report identified FCOIs to the funding agency as required by the regulation (if applicable)
- Alternatively, include in the written subrecipient agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the University to identify, manage and report identified FCOIs to the funding agency (if applicable).

### **Public Accessibility Requirements**

The University shall make its FCOI policy publicly accessible by posting the policy on the University's web site (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.604(a); NIH GPS 4.1.10).

The University shall make available information concerning identified FCOIs held by Investigators and closely-associated individuals publicly accessible prior to the expenditure of funds (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.605(a)(5)(i)-(iv)).

The publicly accessible information shall:

- Include the minimum elements as provided in the regulation;
- Be posted on a Public Website or made available within five (5) business days of a written request (It depends on which option will apply);
- Be updated at least annually on the Website, with responses to a written request also included in the updated information
- Be updated within sixty (60) days of a newly identified FCOI, with responses to a written request also included in the updated information

- Remain available for three (3) years from the date the information was most recently updated.

### **Reporting Requirements for Projects Funded by the U.S. National Institute of Health**

In addition to the stated policy and implementation guidelines, projects funded by the U.S. National Institute of Health shall be subjected to additional reporting requirements.

For projects funded by the U.S. National Institute of Health, the University shall send initial, annual and revised FCOI reports, including all required information defined in the regulation and/or NIH's FAQ H.5 to the NIH via the eRA Commons FCOI Module for the Institute and its subrecipients, if applicable, as required by the regulation and at the following periods (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.604(h); 42 C.F.R. Part 50.605(b); 42 C.F.R. Part 50.605(a)(3)(iii)):

- Prior to the expenditure of funds
- Within sixty (60) days of identification for an Investigator who is newly participating in the project
- Within sixty (60) days for new, or newly identified, FCOIs for existing Investigators
- At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension). The annual report shall provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
- Following a retrospective review to update a previously-submitted report, if new information is discovered following completion of the review.

The University shall notify the U.S. National Institute of Health promptly if bias is found with the design, conduct or reporting of research funded by the U.S. Public Health Service / National Institute of Health and include the requirement to submit a Mitigation Report to explain what action(s) have been or shall be taken to mitigate the effects of the bias in accordance with the regulation (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.605(a)(3)(iii)). The policy and/or procedures shall include all reporting elements (e.g., Entity name, name of the Investigator with the FCOI, nature of SFI(s), value of the SFI(s), etc.) as required by the regulation.

The University shall notify the U.S. National Institute of Health promptly if an Investigator fails to comply with the University's FCOI policy or a FCOI Management Plan appears to have biased the design, conduct, or reporting of the funded research (see U.S. Department of Health and Human Services, 42 C.F.R. Part 50.606(a)). The University shall subsequently take corrective action for noncompliance with the University's FCOI policy or FCOI Management Plan