

**Financial Conflicts of Interest in Public  
Health Service Funded Research**

**University Policy No.:** RH8215  
**Classification:** Research  
**Approving Authority:** President  
**Effective Date:** April 2023  
**Supersedes:** New  
**Last Editorial Change:** n/a  
**Mandated Review:** March 2030

---

**Purpose**

- 1.00 The University recognizes that the advancement and dissemination of knowledge that occurs through conducting research must remain free from bias that may result from conflicts of interest including Financial Conflicts of Interest.
- 2.00 This policy sets out the compliance requirements for research conducted at the University of Victoria (“the University”) with funding from any agency of the US Public Health Services (“PHS”) including the National Institutes of Health (“NIH”) and any other research funding sources as required by US Regulations 42 C.F.R. Part 50 Subpart F “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought”.

**Definitions**

- 3.00 The following definitions apply to this policy:

“**Disclosure**” means a PHS Investigator’s Disclosure of SFI status to the University.

“**Financial Conflict of Interest**” (“**FCOI**”) means an SFI that could directly and significantly affect the design, conduct, or reporting of PHS funded research.

“**Financial Interest**” means anything of monetary value, whether or not the value is readily ascertainable.

“**Institutional Responsibilities**” means a PHS Investigator’s professional responsibilities on behalf of the University, the responsibilities of the PHS Investigator pursuant to the policies, procedures, and rules of the University, and (as applicable) any other responsibilities outlined in the PHS Investigator’s job description, employment agreement, or appointment letter with the University. This may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as the Research Ethics Boards or Data and Safety Monitoring Boards.

“**Manage**” means to take action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

**“PHS”** means the Public Health Service of the U.S. Department of Health and Human Services, and any component of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

**“PHS Awarding Component”** means the organizational unit of the PHS that funds research that is subject to the PHS Regulations.

**“PHS Funded Subrecipient”** means a third-party organization (subcontractor or sub awardee) that receives funding from the University (as the prime awardee) to participate in any research funded by PHS. Monies and responsibilities are passed down to a PHS Funded Subrecipient through a subaward or subcontract that outlines the scope of work, budget, and laws and regulations that the PHS Funded Subrecipient must adhere to.

**“PHS Funded Subrecipient Investigator”** means an investigator who is planning to participate in, or who is participating in any research funded by the Public Health Service through a subaward or subcontract between the University and a PHS Funded Subrecipient.

**“PHS Investigator”** means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, review, or oversight of PHS funded research, or proposed for such funding, which may also include, for example, collaborators and consultants. PHS Investigator also includes senior/key personnel identified as essential to work performance of the study in the contract proposal and contract, or deemed as such by the University in the grant application, progress report, or any other report submitted to the PHS by the University.

PHS Investigator includes the spouse and dependent children of the PHS Investigator.

**“PHS Regulations”** means the US Regulations 42 C.F.R. Part 50 and 45 C.F.R. Part 94, as they may be amended from time to time.

**“PHS Responsible Authority”** means the person(s) designated by the University, through the Vice-President Research and Innovation, to oversee the solicitation and review of Significant Financial Interest Disclosure statements as related to PHS pending applications and funded research.

**“Significant Financial Interest” (“SFI”)** means:

- (a) A Financial Interest consisting of one or more of the following interests of the PHS Investigator (and those of the PHS Investigator’s spouse and dependent children) that reasonably appears to be related to the PHS Investigator’s Institutional Responsibilities:
  - (i) with regard to any publicly traded entity, a Significant Financial Interest 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 \$5,000. 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;

- (ii) with regard to any non-publicly traded entity a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the Disclosure, when aggregated, exceeds \$5,000, or when the PHS Investigator (or the PHS Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
  - (iii) intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests; and
  - (iv) PHS Investigators must also disclose the occurrence of any reimbursed or sponsored travel. (i.e., that which is paid on behalf of the PHS Investigator and not reimbursed to the PHS Investigator so that the exact monetary value may not be readily available), that is related to the PHS Investigator's Institutional Responsibilities, provided, however, that this Disclosure requirement does not apply to travel that is reimbursed or sponsored by a US Federal, State or local government agency, a US institution of higher education, a US academic teaching hospital, a US medical center, or a US research institute that is affiliated with a US institution of higher education.
    - A. This Disclosure will include, at a minimum the purpose of the trip, the identity of the sponsor/organizer, destination the duration and the estimated or exact monetary value. The PHS Responsible Authority(ies) will determine if further information is needed, in order to determine whether the travel constitutes a FCOI with the PHS-funded research.
- (b) "Significant Financial Interest" does not include the following types of Financial Interests:
- (i) salary, royalties, or other remuneration paid by the University to the PHS Investigator if the PHS 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;
  - (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 engagements sponsored by a US Federal, State, or local government agency, a US institution of higher education, a US academic teaching hospital, a US medical center, or a US research institute that is affiliated with a US institution of higher education; and
  - (iv) income from service on advisory committees or review panels for a US Federal, State, or local government agency, a US institution of higher education, a US academic teaching hospital, a US medical center, or a US research institute that is affiliated with a US institution of higher education.

**Scope**

- 4.00 All members of the university community must avoid conflicts of interest, or, where they are unavoidable, declare them in accordance with the relevant policy or collective agreement provisions. This policy applies specifically to PHS Investigators including senior/key personnel who are planning to participate in or are participating in any research funded by the PHS through a grant or through a cooperative agreement

between the University and a PHS Awarding Component or with a PHS awarded institution.

### **Policy**

5.00 This policy:

- (a) describes the Disclosure requirements regarding SFI reporting by PHS Investigators in compliance with the requirements of the PHS Regulations;
- (b) sets out the process by which a PHS Responsible Authority confirms whether an SFI is connected to a PHS Investigator's Institutional Responsibilities and assesses whether it is a FCOI for a PHS Awarding Component-funded project; and
- (c) describes the University's responsibility for managing and reporting FCOIs to the PHS Awarding Component, for informing PHS Investigators of the FCOI directive, and for ensuring compliance with the PHS Regulations.

### **Significant Financial Interest Disclosure**

6.00 All PHS Investigators must complete the Significant Financial Interest Disclosure Form ([SFI disclosure form](#)) to disclose the SFI status of themselves, their spouse/partner, and/or their dependent children.

7.00 PHS Investigators who are new to the University and are transferring PHS funding to the University must disclose their SFI status before funds can be dispersed.

8.00 Initial Disclosure must :

- (a) be made before each PHS funding application is submitted; and
- (b) include all SFIs in the 12 months preceding the Disclosure or declare that none have been received.

9.00 A subsequent Disclosure must be submitted within 30 days of discovering or acquiring a new SFI.

10.00 A renewal SFI Disclosure must be submitted 12 months from the date of the last SFI Disclosure as long as any awarded or pending PHS applications are on file, and must include updated information on any previously disclosed SFIs.

11.00 All Disclosures must be submitted using the forms provided by the University.

12.00 All PHS Investigators who are new to and are applying for and/or receiving PHS funding or who are participating in a PHS-funded research project must make the initial Disclosure and ongoing Disclosures as noted above.

13.00 The PHS Investigator based at the University must identify all other PHS Investigators and consultants who share responsibility for the design, conduct, or reporting of the research including those who join ongoing projects.

- 14.00 The PHS Investigator based at the University must remind other PHS Investigators and consultants of their ongoing responsibility to provide updated information if they obtain any new SFI during the term of the award.
- 15.00 The University, through the Office of Research Services, will collect the SFI forms from PHS Investigators and forward the forms with the disclosed SFI to the PHS Responsible Authority for review and determination of whether there is an FCOI.

#### **Assessment by PHS Responsible Authority**

- 16.00 The PHS Responsible Authority will review a disclosed SFI in conjunction with the project description to determine if:
- (a) any disclosed SFI related to the PHS project; and
  - (b) any SFI is an FCOI.
- 17.00 The PHS Investigator's SFI is related to the PHS research when the PHS Responsible Authority reasonably determines that the SFI could be affected by the PHS-funded research; or is in an entity whose Financial Interest could be affected by the research.
- 18.00 A FCOI exists when the PHS Responsible Authority reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
- 19.00 The review and determination will be conducted prior to the University's expenditure of any funds under the funded research project, and within 60 days of:
- (a) a new PHS Investigator disclosing an SFI;
  - (b) an existing PHS Investigator disclosing a new SFI; or
  - (c) the University identifying that an SFI was not disclosed in a timely manner by the PHS Investigator, or that was not previously reviewed by the University.

#### **Management of FCOI**

- 20.00 If an FCOI is determined to exist, the FCOI Management plan must be prepared by the PHS Responsible Authority to ensure that the FCOI is properly managed.
- 21.00 The FCOI Management plan must specify actions to be taken to Manage the FCOI and include the following key elements:
- (a) role and principal duties of the conflicted PHS Investigator in the research project;
  - (b) conditions of the FCOI Management plan;
  - (c) how the FCOI Management plan is designed to safeguard objectivity in the research project;
  - (d) confirmation of the PHS Investigator's agreement to the FCOI Management plan;
  - (e) how the FCOI Management plan will be monitored to ensure PHS Investigator's compliance; and
  - (f) other information as needed to ensure that the FCOI is properly Managed.

- 22.00 The PHS Responsible Authority will impose, if necessary, interim measures regarding the PHS Investigator's participation in the research project pending completion of the review where an SFI is disclosed during an ongoing research project by a new PHS Investigator or a new SFI by an existing PHS Investigator.
- 23.00 The PHS Investigator must comply with the FCOI Management plan prescribed by the PHS Responsible Authority.
- 24.00 On behalf of the University, the PHS Responsible Authority will implement the FCOI Management plan and monitor compliance with the FCOI Management plan on an ongoing basis until the project is completed.
- 25.00 The University will make information available, promptly upon request, to PHS relating to the SFI Disclosure forms; the University's review of, and response to, such Disclosure; and whether or not the Disclosure resulted in the University's determination of an FCOI. Prior to external Disclosures of information, the University will obtain the PHS Investigator's authorization to disclose information related to the SFI Disclosure form and the University's review of, and response to, such Disclosure to the PHS Awarding Component or a member of a public, which authorization will be contained within the SFI form.

#### **Reporting to PHS and Record Keeping**

- 26.00 The PHS Responsible Authority will send initial, annual, and revised FCOI reports (for the University and for PHS Funded Subrecipients, if applicable) to the PHS Awarding Component at the following times:
- (a) prior to the University's release of any funds under the PHS-funded research project (no report should be sent if the FCOI is eliminated before any funds are spent); and
  - (b) subsequent to the initial FCOI report, during an ongoing research project:
    - (i) within 60 days of identifying a FCOI for the PHS Investigator who is newly participating in the project or a new FCOI for an existing PHS Investigator;
    - (ii) annually at the same time as the annual progress report is due to provide the status of any previously reported FCOI and any changes to the FCOI Management plan (if applicable), until the completion of the project. The report must explain how the FCOI is being managed or why it no longer exists;
    - (iii) following a retrospective review (as per section 32.00 below); and
    - (iv) in the time and manner specified by PHS for any other FCOI reports for the duration of project period (including extensions with or without funds).
- 27.00 The DOI will ensure that FCOI Reports include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI, and to assess the appropriateness of the University's FCOI Management plan. Each report must contain:
- (a) project number;
  - (b) project director/principal PHS Investigator or contact project director/principal PHS Investigator if a multiple project director/principal PHS Investigator model is used;
  - (c) name of the PHS Investigator with a FCOI;

- (d) name of the entity with which the PHS Investigator has a FCOI;
- (e) nature of the FCOI (e.g. equity, consulting fees, travel reimbursement, honoraria);
- (f) value of the Financial Interest per year:
  - (i) US\$0 - US\$4,999;
  - (ii) US\$5,000 - US\$9,999;
  - (iii) US\$10,000-US\$19,999;
  - (iv) amounts between US\$20,000 - US\$100,000 by increments of US\$20,000;
  - (v) amounts above US\$100,000 by increments of US\$50,000; or
  - (vi) a statement that a value cannot be readily determined.
- (g) a description of how the Financial Interest relates to PHS-funded research and the basis for the University's determination that the Financial Interest conflicts with such research; and
- (h) key elements of the University's FCOI Management plan.

28.00 Research Services will retain all records of FCOI Disclosures, and the University's review of, and response to, such Disclosures (whether or not an FCOI is found to exist) and all actions taken under these this policy for at least three years beyond the termination or completion of an award or three years from the date of submission of the final expenditures report, whichever comes later.

#### **Non-Compliance and Retrospective Review**

29.00 PHS Investigators must comply with the terms of their collective agreement (if applicable), the Conflict of Interest Policy (GV0210) and the Scholarly Integrity Policy (AC1105) and their associated procedures, and all other applicable University policies, procedures, and regulations. Non-compliance constitutes misconduct and may be pursued under the applicable collective agreement or University policy. This may result in disciplinary action.

30.00 When the University identifies an SFI that was not disclosed in a timely manner by the PHS Investigator or, for whatever reason, was not previously reviewed by the University during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a PHS Funded Subrecipient), the University, through the PHS Responsible Authority, will, within 60 days:

- (a) review the SFI;
- (b) determine whether it is related to PHS-funded research;
- (c) determine whether a FCOI exists; and
- (d) if so, implement, on at least an interim basis, the FCOI Management plan that shall specify the actions that have been, and will be, taken to manage such FCOI.

31.00 When a FCOI is not identified or managed in a timely manner including:

- (a) failure by the PHS Investigator to disclose an SFI that is determined by the University to constitute a FCOI;
- (b) failure by the University to review or manage such a FCOI; or

(c) failure by the PHS Investigator to comply with the FCOI Management plan,

the University will, within 120 days of the determination of noncompliance, complete a retrospective review of the PHS Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

32.00 The University will document the retrospective review, including, at minimum, the following key elements:

- (a) project number and title;
- (b) project director/principal PHS Investigator or contact project director/principal PHS Investigator if a multiple project director/principal PHS Investigator model is used;
- (c) name of the PHS Investigator with the FCOI;
- (d) name of the entity with which the PHS Investigator has an FCOI;
- (e) reason(s) for the retrospective review;
- (f) detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (g) findings of the review; and
- (h) conclusions of the review.

33.00 Based on the results of the retrospective review, the Office of Research Services or the PHS Responsible Authority will update, if appropriate, the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

34.00 If bias is found, the Office of Research Services will:

- (a) notify the PHS Awarding Component promptly of the corrective action taken or to be taken; and
- (b) submit a mitigation report to the PHS Awarding Component.

The mitigation report must include the elements listed in section 32.00, and must describe the impact of the bias on the project and the University's plan to eliminate or mitigate the effect of the bias. The University's plan will include, at minimum:

- (a) impact on the project;
- (b) extent of harm done, including any qualitative and quantitative data to support any actual or future harm; and
- (c) analysis of whether the project is salvageable.

35.00 After submitting the initial reports described above, the University will submit FCOI update reports annually.

36.00 In any case in which PHS determines that funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment



has been designed, conducted, or reported by the PHS Investigator with an FCOI that was not managed or reported by the University as required by PHS, the PHS Investigator will disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

- 37.00 In cases where Disclosure, reporting, and similar requirements have not been met in a timely manner, the University may suspend financial activity on the grant account or follow the directions provided by PHS.

### **Other University and PHS Investigator Responsibilities: Training, Subcontracting and Public Accessibility of Information**

#### Financial Conflict of Interest Training

- 38.00 The Office of Research Services will provide access to training that covers institutional requirements for SFI Disclosure and the requirements of this policy and will track and monitor completion of the FCOI training module ([FCOI compliance information](#)).

(a) The PHS Investigators will complete the required FCOI training as follows:

- (i) prior to engaging in the PHS-funded research;
- (ii) at least every four years; and
- (iii) immediately when any of the following circumstances apply:
  - A. the FCOI policy or any other applicable policy is revised in any manner that affects the requirements of PHS Investigators;
  - B. the PHS Investigator is new to the University; or
  - C. the University finds that the PHS Investigator is not in compliance with this policy or the FCOI Management plan.

- 39.00 The university must provide training that covers its institutional requirements for SFI Disclosure and the requirements of this policy, and to track and monitor completion of the University training module and the NIH Tutorial.

- 40.00 Both modules are available to PHS Investigators via the FCOI webpage ([FCOI compliance on ORS website](#)):

- 41.00 The NIH tutorial is also available directly from:  
[https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)

#### Subrecipients

- 42.00 When the University carries out PHS-funded research through a subrecipient (e.g., subcontractors or collaborators), the University, through the units responsible for sub-contracts, will take reasonable steps to ensure that the PHS Subrecipient Investigators comply with the FCOI regulations by establishing, in a written agreement with the PHS Subrecipient, whether the PHS Subrecipient Investigators will be subject to the FCOI policy of the PHS Subrecipient or to the University's policies and procedures with respect to the research.

- 43.00 If the PHS Subrecipient's FCOI policy applies, the University will:
- (a) obtain the PHS Subrecipient's certification that its FCOI policy complies with the FCOI Regulations; and
  - (b) specify in the agreement with the PHS Subrecipient a time period for the PHS Subrecipient to report all identified FCOIs of its PHS Investigators to the University that allows the University sufficient time to provide FCOI reports to PHS as required by the FCOI Regulations.
- 44.00 If the University's policies and procedures apply to the PHS Subrecipient, the University will ensure that a written agreement with the PHS Subrecipient specifies that the PHS Subrecipient Investigators must comply with the University's policies and procedures.
- 45.00 The agreement will also specify the time periods for the PHS Subrecipient to submit all PHS Investigator Disclosures of SFIs to the University that allow the University sufficient time to review the SFIs and Manage and report identified FCOIs to the PHS Awarding Component as required by the FCOI Regulations.

#### Public Access to Information

- 46.00 The University shall maintain an up-to-date version of this policy on its publicly accessible website.
- 47.00 At all times after an award has been granted, the University, through the Office of Research Services, shall make available, by written response within five business days of receipt of a request, the information listed below concerning any SFI that meets the following criteria:
- (a) the SFI was disclosed and is still held by the PHS Investigator for the PHS funded research project;
  - (b) The University through the PHS Responsible Authority determines that the SFI is related to PHS funded research; and
  - (c) The University, through the PHS Responsible Authority, determines that the SFI is a FCOI.
- 48.00 The University's written response to a request must include the following minimum information:
- (a) the PHS Investigator's name;
  - (b) the PHS Investigator's position with respect to the research project;
  - (c) the entity with which the PHS Investigator has a FCOI; and
  - (d) value (or estimated value) of the Financial Interest/s per year recorded as:
    - (i) \$0-\$4,999;
    - (ii) \$5,000-\$9,999;
    - (iii) \$10,000-\$19,999;
    - (iv) amounts between \$20,000-\$100,000 in increments of \$20,000;

- (v) amounts above \$100,000 in increments of \$50,000; or
- (vi) a statement that a value cannot be readily determined.

- 49.00 The written response from the PHS Responsible Authority shall note that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the institution's identification of a new FCOI, which should be requested subsequently by the requestor.
- 50.00 The above-noted information, as updated, shall remain available for responses to written requests via the Office of Research Services for at least three years from the date that the information was most recently updated.

**Authorities and Officers**

- 51.00 The authorities and officers for this policy are:
  - (i) Approving Authority: President
  - (ii) Designated Executive Officer: Vice-President Research and Innovation
  - (iii) Procedural Authority: Vice-President Research and Innovation
  - (iv) Procedural Officer: Executive Director, Research Services