

Financial Conflicts of Interest in Public Health Service Funded Research

University Policy No.: RH8215  
Classification: Research  
Approving Authority: President  
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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 a Tm [(3.)0.002inablso6 (na(ha



- (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



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 University0 0 11.04 7mrco(h.(e)-3.239 -1.69



- (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 (see 6.6 (h) 2.7 (n)) (r)-8.9 96.6 (h) 2.7 (n) 10.5 (t) - 0.0 [

(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);



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 ([FC3 \(r\)-6 \(a4.6 \(lr\)-6 \(l MC ET](#)

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

- (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