PROCEDURES PERTAINING TO FINANCIAL COI IN US PUBLIC HEALTH SERVICE FUNDED RESEARCH

**1.0 PURPOSE**

1.1 These Procedures define the compliance requirements for research conducted at Simon Fraser University (“SFU”) with funding from any agency of US Public Health Services (“PHS”), including National Institutes of Health (“NIH”), and any other research funding sources which have adopted the requirements of US 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" (“FCOI Regulations”).

1.2 In addition to compliance with applicable University policies and procedures, the PHS Investigators (as defined below), who are applying for and/or receiving PHS funding or who are participating in the PHS-funded research project, either as an awardee or sub-recipient, must comply with these Procedures.

**2.0 DEFINITIONS**

2.1 See Appendix A to the Conflict of Interest and Conflict of Commitment Policy (GP 37) for definitions of words used in the policy and in these procedures.

**3.0 PROCEDURE**

**Significant Financial Interest (“SFI”) Disclosure By The PHS Investigator**

3.1 The PHS Investigator must complete the SFI form provided by Research Services to disclose an SFI of the individual, his/her/their spouse or domestic partner, and any dependent children or to confirm that none exists at the following times:

3.1.1 The initial disclosure must:

   a. be made before the time of application for PHS-funded research; and
b. include all SFIs in the 12 months preceding the disclosure.

3.1.2 A subsequent disclosure must occur:

a. within 30 days of discovering or acquiring a new SFI before the start or during the term of the PHS-funded research, and

b. on an annual basis (no later than 12 months from the date of the last SFI disclosure) during the term of the PHS-funded research, disclosing:

   i. all SFIs received in the 12 months preceding the disclosure that were not previously reported; and

   ii. updated information regarding any previously disclosed SFI.

3.1.3 All PHS Investigators who are new to SFU 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.

3.1.4 The PHS Investigator based at SFU 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.

3.1.5 The PHS Investigator based at SFU 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.

3.1.6 SFU, through the Director, Research Services or their delegate, 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.

**FCOI Training**

3.2 Research Services will provide training that covers the requirements of this Procedure and FCOI regulations and will track and monitor completion of the FCOI training module.

3.3 The PHS Investigators will complete the required FCOI training as follows:

3.3.1 prior to engaging in the PHS-funded research;

3.3.2 at least every four years; and

3.3.3 immediately when any of the following circumstances apply:

   a. SFU revises SFU Policy on Conflict of Interest and Conflict of Commitment (Policy GP 37), these Procedures or any other applicable policy in any manner that affects the requirements of PHS Investigators;

   b. the PHS Investigator is new to SFU; or

   c. SFU finds that the PHS Investigator is not in compliance with these Procedures or the FCOI management plan.
Assessment by Designated Official and Management of FCOI

3.4 The PHS Responsible Authority will review a disclosed SFI in conjunction with the project description to determine whether:

3.4.1 any disclosed SFI is related to the PHS project; and
3.4.2 any SFI is an FCOI.

3.5 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.

3.6 An 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.

3.7 The review and determination will be conducted prior to SFU’s expenditure of any funds under funded research project, and within 60 days of:

3.7.1 a new PHS Investigator disclosing an SFI;
3.7.2 an existing PHS Investigator disclosing a new SFI; or
3.7.3 SFU identifying that an SFI was not disclosed in a timely manner by the PHS Investigator, or that was not previously reviewed by the University.

3.8 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. The FCOI management plan must specify actions to be taken to Manage FCOI and include the following key elements:

3.8.1 role and principal duties of the conflicted PHS Investigator in the research project;
3.8.2 conditions of the FCOI management plan;
3.8.3 how the FCOI management plan is designed to safeguard objectivity in the research project;
3.8.4 confirmation of the PHS Investigator’s agreement to the FCOI management plan;
3.8.5 how the FCOI management plan will be monitored to ensure PHS Investigator’s compliance; and
3.8.6 other information as needed to ensure that the FCOI is properly managed.

3.9 Conditions or restrictions that might be imposed to Manage an FCOI include, but are not limited to:

3.9.1 public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
3.9.2 for research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

3.9.3 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;

3.9.4 modification of the research plan;

3.9.5 change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

3.9.6 reduction or elimination of the Financial Interest (e.g., sale of an equity interest); or

3.9.7 severance of relationships that create financial conflicts

3.10 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.

3.11 The PHS Investigator must comply with the FCOI management plan prescribed by the PHS Responsible Authority.

3.12 On behalf of SFU, the PHS Responsible Authority will implement the FCOI management plan and monitor compliance with the FCOI management plan on an ongoing basis until the completion of the project.

3.13 SFU will make information available, promptly upon request, to PHS relating to the SFI disclosure forms, University’s review of, and response to, such disclosure, whether or not the disclosure resulted in the University’s determination of an FCOI should PHS request it. Prior to external disclosures of information, SFU will obtain the PHS Investigator’s authorization to disclose information related to the SFI disclosure form, 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**

3.14 Research Services will send initial, annual and revised FCOI Reports (for SFU and for sub-recipients, if applicable) to the PHS awarding component at the following times:

3.14.1 prior to SFU’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);

3.14.2 within 60 days of identification of an FCOI for the PHS Investigator who is newly participating in the PHS-funded project or a new FCOI for an existing PHS Investigator;

3.14.3 annually at the same time as the annual progress report is due or at time of extension to provide the status of any previously reported FCOI and any changes to the FCOI management plan (if applicable), until the completion of the PHS-funded project. The report must explain how the FCOI is being managed or why it no longer exists;
3.14.4 following a retrospective review (as per section 3.17 below); and

3.14.5 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).

3.15 Research Services will ensure that FCOI Reports include sufficient information to enable the PHS awarding component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the University’s FCOI management plan. Each report must contain:

3.15.1 project number;

3.15.2 project director/principal PHS Investigator or contact project director/principal PHS Investigator if a multiple project director/principal PHS Investigator model is used;

3.15.3 name of PHS Investigator with an FCOI;

3.15.4 name of the entity with which the PHS Investigator has an FCOI;

3.15.5 nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria);

3.15.6 value of the Financial Interest per year recorded as:
   a. US$0 - US$4,999;
   b. US$5,000 - US$9,999;
   c. US$10,000-US$19,999;
   d. amounts between US$20,000 - US$100,000 by increments of US$20,000;
   e. amounts above US$100,000 by increments of US$50,000; or
   f. 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 as outlined in 3.8 above.

3.16 Research Services will retain all records of FCOI disclosures, and SFU’s review of, and response to such disclosures (whether or not an FCOI is found to exist) and all actions taken under these Procedures for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

Non-Compliance and Retrospective Review

3.17 PHS Investigators must comply with Policy GP 37, its associated procedures and other applicable University policies. Non-compliance with the policies constitutes misconduct and may be pursued under the applicable collective agreement or University policy. Under SFU Policy on Responsible Conduct of Research (R 60.01), failure to manage an SFI in conformance with the applicable policies may result in disciplinary action.
3.18 When SFU identifies an SFI that was not disclosed timely by the PHS Investigator or, for whatever reason, was not previously reviewed by SFU during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), SFU, through the PHS Responsible Authority, will, within 60 days:

3.18.1 review the SFI;
3.18.2 determine whether it is related to PHS-funded research;
3.18.3 determine whether an FCOI exists; and,
3.18.4 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 financial conflict of interest going forward.

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

3.19.1 failure by the PHS Investigator to disclose an SFI that is determined by SFU to constitute an FCOI;
3.19.2 failure by SFU to review or manage such an FCOI; or
3.19.3 failure by the PHS Investigator to comply with the FCOI management plan.

3.20 SFU will, within 120 days of SFU’s 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.

3.21 SFU will document the retrospective review, including, at minimum, the following key elements:

3.21.1 project number and title;
3.21.2 project director/principal PHS Investigator or contact project director/principal PHS Investigator if a multiple project director/principal PHS Investigator model is used;
3.21.3 name of the PHS Investigator with the FCOI;
3.21.4 name of the entity with which the PHS Investigator has an FCOI;
3.21.5 reason(s) for the retrospective review;
3.21.6 detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
3.21.7 findings of the review; and
3.21.8 conclusions of the review.

3.22 Based on the results of the retrospective review, Research Services will update, if appropriate, the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.
3.23 If bias is found, Research Services will:

3.23.1 notify the PHS awarding component promptly of the corrective action taken or to be taken; and

3.23.2 submit a mitigation report to the PHS awarding component; the mitigation report must include, at a minimum, the key elements documented in the retrospective review above, a description of the impact of the bias on the research project and the University’s plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

3.24 After submitting the initial reports described in sections 3.22 and 3.23 above, SFU will submit FCOI update reports annually, as specified in section 3.14 above.

3.25 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.

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

Public Accessibility of Information

3.27 SFU will post and maintain Policy GP 37 and Procedures on the publicly accessible website.

3.28 Upon request, SFU, through Research Services, will make available information concerning any SFI disclosed to SFU that meets the following criteria:

3.28.1 a disclosed SFI, which is held by the PHS Investigator, identified by SFU as senior/key personnel for the PHS-funded research;

3.28.2 SFI that is related to the PHS-funded research as determined by the PHS Responsible Authority; and

3.28.3 any FCOI determined by the PHS Responsible Authority.

3.29 The information will be provided through a written response within 5 business days of receipt of a written request and include up-to-date information and the following elements:

3.29.1 name of the PHS Investigator with the FCOI;

3.29.2 PHS Investigator’s title and role with respect to the research project;

3.29.3 name of the entity in which the SFI is held;
3.29.4 nature of the SFI; and

3.29.5 the approximate dollar value of the SFI recorded as $US0-$US4,999; $US5,000-$US9,999; $US10,000-$US19,999; amounts between $US20,000-$US100,000 by increments of $US20,000; amounts above $US100,000 by increments of $US50,000; 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.

3.30 The written response will state 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 SFU’s identification of a new FCOI, which should be requested subsequently by the requestor.

3.31 Information concerning the SFI shall remain available for at least 3 years from the date the information was most recently updated.

Requirements Regarding Subrecipients

3.32 When SFU carries out PHS-funded research through a subrecipient (e.g., subcontractors or collaborators), SFU, 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’s 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.

3.33 If the PHS Subrecipient’s FCOI policy applies, SFU will:

3.33.1 obtain the PHS Subrecipient’s certification that its FCOI policy complies with the FCOI Regulations; and

3.33.2 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 SFU that allows SFU sufficient time to provide FCOI reports to PHS as required by the FCOI Regulations.

3.34 If the University’s Policies and Procedures apply to the PHS Subrecipient, SFU 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. 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.

3.35 SFU will provide FCOI reports to the PHS Awarding Component regarding all FCOI of all Subrecipient Investigators consistent with this subpart prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.