

Simon Fraser University

Procedures pertaining to US Public Health Services Grants

GENERAL

Investigators seeking funding from the US National Institutes of Health (NIH) must disclose all **Significant Financial Interests** that would reasonably appear to be related to the Investigator's institutional responsibilities. The institution is required to determine whether a **Financial Conflict of Interest** exists in respect to the proposed research and if so, to develop and implement a **Management Plan** that may include its reduction or elimination. Under NIH regulations, an institution may not submit an NIH grant application nor can an award be issued to that institution until each Investigator identified in the application or subsequently identified has made a disclosure of Significant Financial Interests to their institution.

Prior to engaging in NIH funded research, each Investigator is required to have completed financial conflict of interest training and to repeat this training at every four years. For details regarding these NIH requirements, see <http://grants.nih.gov/grants/policy/coi/>.

DEFINITIONS

Investigator: (also referred to as Senior or Key Personnel as indicated in the grant application, Notice of Award and any report submitted to NIH):

Investigator means the Project Director or Principal Investigator and *any other person*, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding, which may include collaborators or consultants who provide professional advice or services for a fee.

Institutional Responsibilities:

An Investigator's professional responsibilities on behalf of the Institution including teaching, research, research consultation, professional practice, institutional committee memberships, etc. At SFU, tenure-track faculty responsibilities are outlined in **Policy A30.03**.

Significant financial interest means:

- (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:
 - (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. 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;
 - (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 Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. The threshold of \$5,000 applies.

- (2) Investigators must disclose payment for services where the service is related to their institutional responsibilities and the annual amount is greater than \$5,000. Such payment must be disclosed within 30 days once the \$5,000 threshold has been reached within a twelve-month period.
- (3) Investigators have an ongoing obligation to disclose Significant Financial Interests of themselves, their spouses, and their dependent children, which are related to their university responsibilities, both at the time of application for a PHS or NIH grant and throughout the awarded period. Investigators must update financial disclosures of Significant Financial Interests to their Institutions within thirty days of acquiring or discovering that SFI.
- (4) Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities if the source of reimbursement is a company or industry. For travel reimbursed by non-industry sources, investigators must disclose the occurrence of any non-industry reimbursed or sponsored travel related to their institutional responsibilities only when the annual aggregated amount paid to the specific investigator exceeds \$5,000 per entity. 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, an US academic teaching hospital, an US medical center, or a US research institute that is affiliated with a US institution of higher education.

Disclosure will include, at a minimum: the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration. Note: Disclosure requirements also apply to reimbursed or sponsored travel received by the Investigator's spouse and dependent children that is related to the Investigator's institutional responsibilities.

- (5) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights. Nor does the term include 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.

The term significant financial interest does not include income from seminars, lectures, or teaching engagements sponsored by a US government agency, a US institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a US institution of higher education; or income from service on advisory committees or review panels for a US government agency, an institution of higher education, academic teaching hospital, medical center, or research institute that is affiliated with a US Institution of higher education. Nor does the term include similar income from non-US equivalents of these entities where the annual aggregated amount paid to the specific investigator does not exceed \$5,000 per entity.

Financial Conflict of Interest (FCOI) is a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of the NIH funded research.

DISCLOSURE by the Investigator/Collaborator/Consultant

Prior to submission of an NIH application, each SFU based Investigator and those not otherwise covered by their own organization's FCOI procedures, must complete an SFU Statement of Significant Financial Interests as defined above. Should the grant be awarded, their Statement of Significant Financial Interests will be required annually during the award period or within 30 days of acquiring or discovering a new Significant Financial Interest. The SFU Statement of Financial Interests is a form used to confirm the presence of a Significant Financial Interest or to confirm that none exists. Reporting on that form is required for financial interests of the individual, his/her spouse or domestic partner, and any dependent children in as much as these relate to the individual's professional responsibilities on behalf of SFU.

The Vice President, Research will review disclosed Significant Financial Interests in conjunction with the project description for the purpose of determining whether a disclosed Significant Financial Interest relates to the research for which NIH funding is sought and constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest is determined to exist, the NIH investigator based at SFU and those not otherwise covered by their own organization's FCOI procedures, will follow SFU Policy GP 37 disclosure procedures, and the University will ensure that NIH requirements for managing, mitigating, or eliminating conflict are carried out.

Collaborators from other institutions who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a sub-grant or subcontract from SFU are expected to comply with the policies and procedures for disclosure and review of any Significant Financial Interests at the institution at which they are employed. Those institutions are responsible for reviewing those disclosures and, if conflicts are identified, for sending SFU assurances of their ability to manage, reduce or eliminate the conflicts. SFU will require collaborators to provide annual updates.

The information provided in disclosure forms may be released to NIH should NIH request it.

DISCLOSURE: By SFU of Identified FCOI

Prior to spending NIH funds and during the tenure of a grant, any Significant Financial Interests that have been identified under these procedures as conflicting will be reviewed, and managed, reduced, or eliminated, at least on an interim basis, and notification will be provided to NIH within sixty days of identification. NIH may request from SFU details of the conflict, including the name of the Investigator and the name of any entity with which the Investigator has an FCOI.

SFU is required to make available to public inquiry certain information concerning identified Financial Conflicts of Interest either via a website or by written response within five business days.

Records of financial disclosures, Vice President Research's determination, and University action regarding management of conflicts of interest will be retained in the Office of Research Services 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

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.

SFU Investigators found to be non-compliant with these procedures will be required to undergo a retrospective review of their Significant Financial Interests and will be required to disclose their Financial Conflict of Interests in each public presentation of the results of research and to request an addendum to previously published presentations.

Non-compliance with SFU Policy on Conflict of Interest ([GP 37](#)) and its associated procedures constitutes misconduct and may be pursued under the applicable collective agreement or University Policy. Under SFU Policy on Integrity in Research and Misconduct in Research ([R 60.01](#)), failure to conduct research in strict observance of ethical standards, including not disclosing a Financial Conflict of Interest, is an offense that is subject to a range of disciplinary measures up to and including dismissal or expulsion.

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RESPONSIBILITIES AND ACTIONS

RESPONSIBILITY	ACTION
Principal Investigator (PI)	<p>Identifies all other Investigators and Consultants who share responsibility for the design, conduct or reporting of the research including those who join ongoing projects.</p> <p>Reminds other Investigators and Consultants of their ongoing responsibility to provide updated information if they obtain any new Significant Financial Interests during the term of the award.</p>
All Investigators	<p>Complete the SFU Investigator’s Statement of Financial Interests disclosure certifying that either no Significant Financial Interests exists or that a complete listing of all Significant Financial Interests has been provided. The PI and all other Investigators must disclose their Significant Financial Interests and those of their spouse and dependent children over the previous twelve month period no later than at the time of application for funding. If the project is funded, the Disclosure Form must be submitted at least annually or within thirty days of acquiring or discovering a new Significant Financial Interest.</p> <p>All prospective and current Investigators are expected to complete required FCOI training prior to engaging in NIH supported research.</p> <p>Investigators must report annually to the Associate Director, Research Contracts in the Office of Research Services any directly reimbursed or directly sponsored travel expenses for travel relating to their university responsibilities, as soon as the combined value of all trips sponsored or reimbursed by the same entity within a twelve month period exceeds \$5,000. Certain exceptions apply – see Procedures. The information will be used to determine whether the travel constitutes an FCOI with the NIH funded research.</p>
Collaborators working on the SFU-led project under sub-grants or subcontracts with other institutions	<p>Must comply with their employing institution’s policies and procedures on completion and review of financial disclosures, and have their institutions send assurance of review to the Associate Director for Research Contracts and Foreign Grants in the Office of Research Services. These assurances should identify the contract/grant number, the name of the PI, the name of the Investigator with the Significant Financial Interests, whether the Significant Financial Interest was found to constitute a Financial Conflict of Interest and if so, how that conflict of interest will be managed, reduced or eliminated. The collaborating institution will notify the SFU Associate Director for Research Contracts and Foreign Grants if it determines that an Investigator based at their institution has been found to have a Financial Conflict of Interest with the research project.</p>

RESPONSIBILITY	ACTION
Collaborators or consultants	Non-university based collaborators or consultants who have responsibility for the design, conduct, or reporting of research will be asked to complete the SFU Statement of Financial Interests in order to allow SFU to determine the existence of a financial conflict of interest.
<p>SFU Office of Research Services – Associate Director for Research Contracts and Foreign Grants</p> <p>Carries out tasks on behalf of the Vice President, Research</p>	<p>Obtains an Investigator’s Statement of Financial Interest from each Investigator named in an NIH application.</p> <p>Ensures that all Investigators and consultants identified on an NIH Notice of Award and those who are later added to the project have completed the required Financial Conflict of Interest training.</p> <p>Incorporates as part of sub- agreement terms that establish whether the FCOI policy of SFU or that of the sub recipient will apply to sub recipient investigators.</p> <p>Notifies NIH promptly if an Investigator fails to comply with NIH procedures or if a Financial Conflict of Interest appears to have biased the design, conduct, or reporting of the NIH-funded research. Files Mitigation Reports at the request of the Vice President, Research.</p> <p>Obtains further information or clarification as required to review an Investigator’s Statement of Financial Interests disclosure.</p> <p>Obtains, reviews and submits annual reports from those Investigators for whom a Financial Conflict of Interest was identified and mitigated or managed to ensure continued compliance.</p> <p>Makes available to public inquiry certain information concerning identified Financial Conflicts of Interest by written response within five business days.</p>
Chair/Faculty Dean (the Reviewer in GP 37)	Formulates a plan for managing, reducing or eliminating an identified Financial Conflict of Interest. Specifically addresses the issue of safeguarding objectivity in research and clarifies how the plan will be monitored to ensure ongoing compliance. Annually reviews the status of existing Management Plans in their department and provides a report to the Associate Director for Research Contracts and Foreign Grants for incorporation into the University’s annual report to NIH.