



Form 1 Information Sheet: UBC Significant Financial Interest (SFI) Disclosure & Consent Form for Research Funded by the US Public Health Service (PHS)

Purpose: You will need to complete Form 1 if you are a UBC investigator and UBC is either the Prime Awardee or a Subrecipient but following UBC FCOI policy. **If you are NOT a UBC investigator, but are following UBC FCOI policy, please complete [Form 3](#).**

Context: Effective August 24, 2012, US Regulations 42 C.F.R. Part 50 and 45 C.F.R. Part 94 (the PHS FCOI Regulations) established requirements to ensure that research funded by the US Public Health Service (PHS), which includes the National Institutes of Health (NIH), is free from bias resulting from financial conflicts of interest (FCOI). Pursuant to the PHS FCOI Regulations, everyone who qualifies as an Investigator must meet reporting and training requirements at the time of proposal and during the life of the award. This includes disclosure of significant financial interests (SFIs) in order to assess whether a financial conflict of interest exists which could erode the integrity of the PHS funded research.

For the purposes of the PHS FCOI Regulations, "Investigator" is defined as: ***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 PHS, or proposed for such funding, which may also include, for example, collaborators and consultants.***

Please note that the obligation to disclose extends to SFIs held by the Investigator's spouse and dependent children as well as to those held by the Investigator.

SFI Disclosure is an ongoing obligation for as long as an Investigator is applying for, holding or working on a PHS funded grant. Every person who qualifies as an Investigator under the PHS FCOI Regulations is required to disclose Significant Financial Interests (SFIs) **before each** funding application is submitted to a PHS awarding component, within 30 days of a new significant financial interest being acquired, and **annually** while applying for or participating in PHS funded research.

Upon completion, please submit Form 1 to the UBC Designated Institutional Official (DIO) at: US.FCOI@ubc.ca.

Instructions

Reason for Disclosure

Investigators are required to complete and submit a Form 1:

- a. **before** submitting a grant to a PHS Agency (includes NIH) or to a funding agency that requires compliance with the PHS FCOI Regulations
- b. **annually**, while participating in PHS funded research
- c. **within 30 days** of the development of a new significant financial interest
- d. **before** participating as a new Investigator in on-going PHS funded research

Grants initially awarded prior to the implementation date of the PHS FCOI Regulations (August 24, 2012) are not immediately subject to the requirements. HOWEVER, this exemption ends with any **supplemental, extension or additional funding** on those grants. As such, and prior to the release of any such funds, Investigators will be required to submit a completed Form 1.

Status of the Grant

This section asks you to provide some information on the status of the grant for which Form 1 is being submitted.

Specifically, you are asked to indicate whether (a) you are submitting in relation to a grant application OR an awarded grant, AND (b) UBC is the Prime Awardee (applying/receiving the grant funding directly from the PHS Awarding Component) OR a Subrecipient (applying/receiving the PHS grant funding through another university or research institution).

Part 1: Project Information

Please provide the **full title** of the Project and the Grant Number (if awarded). The Grant Number is generated by the funding agency and has the following form: 5 R01 HL123451-01A2.

Please identify the PHS Awarding Component/Sponsor. For a list of PHS Funding Agencies, click [here](#). Please note this list also includes some non-PHS funding agencies who require compliance with PHS FCOI Regulations. This list is provided for your convenience; however, as other funding agencies may decide to adopt the PHS FCOI requirements, it is your responsibility to check whether your funding agency requires compliance.

Provide the UBC FAS# (if known). This number is generated by UBC Grant Administration when they receive the grant application, and has the following form: F14-01234.

Provide the name and institutional affiliation for the Prime Awardee Principal Investigator (i.e. the lead Investigator and the Institution that will be receiving the funding directly from the PHS Awarding Component). This may be a UBC Investigator, or it may be an Investigator from another institution.

If UBC is NOT the Prime Awardee, please also provide the name and email address for the UBC Principal Investigator.

Part 2: Investigator Information

Please indicate your role on the study, i.e. whether you are either the UBC PI or a UBC Investigator, your contact information and the date.

Part 3: Other Investigator Information

If you are not the UBC Principal Investigator, please do not fill in Part 3.

The US Regulations require **all** individuals who meet the definition of Investigator (see Context section above) to submit significant financial interest disclosures. The UBC Principal Investigator (i.e. the lead Investigator at UBC) is required to provide a list of individuals who meet this definition so that UBC can confirm that all necessary steps have been taken to ensure compliance initially prior to grant submission, prior to the disbursement of funding where the grant application is successful and for the duration of the study. This section only needs to be completed if you are the UBC PI for this study. The UBC PI must select ONE of the options (listed below).

A [List of Investigators](#) is required as part of the Grant Application process if there are Investigators other than the PI involved with the grant. If UBC is the prime awardee and there are no Investigators other than the PI involved with the grant, please select the first option. If UBC will be a subrecipient and there are no Investigators other than the PI involved with the UBC portion of the grant, please select the second option. If there are other Investigators involved with the grant, and there have been no changes to the previously submitted list, please select the third option. If there are other Investigators involved with the grant, but a List of Investigators has not been provided, or if there have been changes to the list, please select the fourth option and submit the current List of Investigators with the SFI disclosure form.

- a. UBC is the prime awardee and there are NO Investigators other than the PI on this grant application/study OR
- b. UBC is a subrecipient and there are NO Investigators (other than the PI) on the UBC portion of the grant application/study OR
- c. There have been no changes to the List of Investigators previously submitted OR
- d. A current List of Investigators is attached (see Step 4 of the [ORS E-Submission Procedures](#)).

Part 4: Disclosure Information

This portion of the form requests specific information pertaining to your, your spouse/partner's and your dependent children's financial interests.

Please note that you must complete 4.1-4.4 and sign the Consent Form on page 4 if:

- a. This is the first time you have ever filed a SFI Disclosure Form with UBC; OR
- b. You have not filed an SFI Disclosure Form with UBC in relation to this or any other project within the past 12 months; OR
- c. You have filed an SFI Disclosure Form with UBC within the past 12 months in relation to either this or another project, AND there has been a change in your Significant Financial Interests since your last SFI disclosure.

However, if you have filed an SFI Disclosure Form with UBC within the past 12 months in relation to either this or another project, AND there has been NO change in your Significant Financial Interests since your last SFI disclosure, then you may answer 4.A, skip 4.1–4.3, **but complete 4.4** as appropriate, and sign the Consent Form on page 4.

4.A No change in Significant Financial Interests

As explained immediately above, please ONLY answer this question if there has been NO change in your Significant Financial Interests AND your most recently submitted SFI Disclosure Form is dated within the past 12 months.

4.1 Publicly Traded Entities: Income and Equity Interests

Provide information pertaining to income received and/or equity held in publicly traded organizations over the prior twelve months, that **when aggregated** exceed \$5,000 **and** which reasonably appear to be related to your institutional responsibilities. Related to your institutional responsibilities means related to your professional responsibilities on behalf of UBC and as defined by UBC in its policy on financial conflicts of interest, which includes research, research consultation, teaching, professional practice, institutional committee memberships and service on panels such as Research Ethics Boards and Safety Monitoring Boards. It also includes outside commitments which require disclosure pursuant to [UBC's Policy 97 Conflicts of Interest and Commitment](#). Simply holding shares in a publicly traded company that has no relation to your professional responsibilities/declared outside commitments does **not** require disclosure.

4.2 Non-Publicly Traded Entities

a. Income

Provide information pertaining to income or other payment/ remuneration received from any non-publicly held organizations/entities in the prior twelve months, if the value of the remuneration received **when aggregated** exceeds \$5,000, **and** if that remuneration reasonably appears to be related to your institutional responsibilities/declared outside commitments.

b. Equity

Provide information pertaining to any equity held in any non-publicly held organizations / entities over the prior twelve months, **irrespective of** the value of the equity, where it reasonably appears to be related to your institutional responsibilities/declared outside commitments.

4.3 Intellectual Property Rights and Interests

Provide information with respect to any intellectual property rights and interests (e.g. patents, copyrights) **upon receipt of income related to such rights and interests** and provided that the rights and interests reasonably appear to be related to your institutional responsibilities/declared outside commitments.

4.4 Travel Reimbursement and Sponsorship

Provide details related to any reimbursed or sponsored travel in the last 12 months which would reasonably appear to be related to your institutional responsibilities, where the total amount from any one entity (for-profit or non-profit) exceeds \$5000.

Please remember that any sponsored or reimbursed travel exceeding an aggregate total of \$5,000 from a single entity is subject to the 30 day reporting requirement. This means that where an entity sponsors or reimburses multiple trips within the reporting period, as soon as the total amount sponsored or reimbursed for those trips exceeds \$5000, the monetary value and details of those trips (as outlined in 4.4) must be reported within 30 days.

This disclosure requirement does NOT apply if the travel costs were reimbursed or sponsored by a Federal, state or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

For specific information pertaining to the exact application of this requirement, please contact US.FCOI@ubc.ca.

Consent and Submission

Please carefully review the consent which provides that if required, your personal information may be provided to the PHS Funding Agency in the United States, and that in certain circumstances, it may be required to be made publicly available at the request of a member of the public. It also confirms your right to withdraw your consent at any time.

Please submit the Form 1 via e-mail to US.FCOI@ubc.ca. Specific questions can be addressed by Wendy Bond, at 604-822-4581. UBC's Designated Institutional Official for US conflict of interest matters is Nina Preto, who can be contacted by phone at 604-827-5597.