#### Office of Research Ethics (US - FCOI)

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# Form 3 Information Sheet: Subrecipient/External Investigator Significant Financial Interest Disclosure & Consent Form for Research Funded by the US Public Health Service (PHS)

Purpose: The following instructions are to assist with the completion of Form 3.

Please complete this form if you are either a Subrecipient Investigator (i.e., your institution is receiving PHS funding through UBC for this grant) or an External Investigator (i.e., you are collaborating with a UBC investigator, but neither you nor your institution are receiving PHS funding for this grant), AND you are following UBC FCOI policy. If you are a UBC investigator, please complete Form 1.

Context: Effective August 24, 2012, US Regulations 42 C.F.R. Part 50 and 45 C.F.R. Part 94 (the PHS FCOI Regulations) establish 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 certain reporting and training requirements at the time of proposal and during the life of the award. This includes disclosure of significant financial interests (SFIs) so that these may be assessed to determine whether a financial conflict of interest that could erode the integrity of the PHS funded research exists.

For the purposes of the US 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 US 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 3 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 3:

- 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 3.

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#### Status of the Grant

This section asks you to provide some information on the status of the grant for which the Form 3 is being submitted.

Specifically, you are asked to indicate (a) whether your Form 3 is being submitted in relation to a grant application OR an awarded grant AND (b) whether UBC is the Prime Awardee (i.e., is or will be receiving the grant funding directly from the PHS Awarding Component) or a Subrecipient (i.e., is or will be 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 known). The Grant Number is generated by the funding agency and has the following form: 5 R01 HL123451-01A2.

Please indicate who the PHS Awarding Component/Sponsor is.

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

Provide the name of the UBC Principal Investigator.

# **Part 2: Investigator Information**

Please indicate your role on the study, i.e. whether you are the Subrecipient PI, a Subrecipient Investigator or an External Investigator (not funded).

Please also provide your name, institution and contact information, the name of the subrecipient PI (if not you), and the date.

## **Part 3: Other Investigator Information**

The US Regulations require **all** individuals who meet the definition of Investigator (see Context section above) to submit significant financial interest disclosures. This section asks that the Subrecipient or External PI provide a list of all the Investigators working with them on the sub-application/subaward, including any External Investigators (not paid).

If there are no Investigators working on the subaward grant application or study other than the Subrecipient PI, please select "No Investigators."

If you are not the Subrecipient/External Principal Investigator, you are NOT required to complete this section of the form.

#### 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.

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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 the subrecipient/external institution, and includes research, research consultation, teaching, professional practice, institutional committee memberships and service on panels such as Research Ethics Boards and Safety Monitoring Boards. Simply holding shares in a publicly traded company that has no relation to your professional responsibilities 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.

#### 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.

## 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 appear to be reasonably related to your institutional responsibilities.

#### 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.

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# **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 3 via e-mail to <u>US.FCOI@UBC.ca</u>. 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.

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