# U.S. Public Health Service Financial Conflict of Interest Requirements

## APPENDIX B

## SIGNIFICANT FINANCIAL INTEREST DISCLOSURE FORM

## APPLICABLE TO AN AWARD FROM A U.S. PUBLIC HEALTH SERVICE AWARDING AGENCY

**Investigator’s Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Investigator’s Department:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Investigator’s Email:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Telephone**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Sponsor’s Name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Project/Proposal Title**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**This Disclosure is:**

🞏 my initial Disclosure at the time of grant application 🞏 a change to my most recent Disclosure

🞏 my annual Disclosure 🞏 an addendum **for travel purposes only** to my most recent Disclosure

**Purpose:**

The form you are about to complete was designed for you to satisfy the disclosure requirements mandated by the U.S. Public Health Service (PHS) regulations ([42 CFR Part 50 and 45 CFR Part 94](https://www.govinfo.gov/content/pkg/CFR-2011-title42-vol1/pdf/CFR-2011-title42-vol1-part50-subpartF.pdf)) on *Promoting Objectivity in Research.* This Disclosure should reflect those significant financial interests that reasonably appear to be are related to your organizational responsibilities at the University of Guelph.

Upon completion, please return this form to the secretary for the Designated Institutional Officials: Matt Frontini, mfrontin@uoguelph.ca.

**Publicly Traded Entities:** In accordance with PHS regulations, a *significant financial interest (“SFI”)* exists if the value of any remuneration received from any publicly traded 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, and that such entity is, or would appear, to be reasonably related to your organizational responsibilities.

*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.*
1. **(a) During the past 12 months, did you, your spouse or your dependent children receive *remuneration* such as consulting fees, honoraria, speaker fees, advisory board fees from ANY publicly traded *entity* that when combined amounted to greater than $5,000 (U.S. dollars) and which publicly traded entity is, or would appear, to be reasonably related to your organizational responsibilities?**

*Because PHS regulations do not exclude income from authorship activities, you must include them in your response to this question. Please do* ***not*** *include equity, royalties or other payments on intellectual property rights in your response to this question.*

**NO \_\_\_\_ YES \_\_\_\_** If yes, complete table below

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Entity** | **Type of Business** | **Amount in U.S. Dollars** | **Activity** | **Individual Receiving Remuneration:****You/Spouse/Dependent Children** |
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**(b) As of the date of this disclosure, do you, your spouse or your dependent children hold any *equity* interests in a publicly-traded *entity* that is, or would appear, to be reasonably related to your organizational responsibilities? If so, does the value of this *equity* exceed $5,000 (U.S. dollars) either on its own OR when combined with any other remuneration from the same *entity*?**

**NO \_\_\_\_ YES \_\_\_\_** If yes, complete table below

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| --- | --- | --- | --- | --- |
| **Name of Entity** | **Type of Business** | **Type of Equity** | **Value in U.S. Dollars** | **Individual Holding the Equity:****You/Spouse/Dependent Children** |
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**Non-Publicly Traded Entities**  According to PHS regulations, a *significant financial interest* exists if the value of any remuneration received from any non-publicly traded entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000 (in U.S. dollars), or when you (or your spouse or dependent children) holds any equity interest in the same entity and that such entity is, or would appear, to be reasonably related to your organizational responsibilities.

*For purposes of the PHS regulations and this question, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship). Equity interests include stock, stock options, or other ownership interests.*

**2. (a) During the past 12 months, did you, your spouse or your dependent children receive any remuneration from ANY non-publicly traded *entity* that is, or would appear, to be reasonably related to your organizational responsibilities, and that when combined amounted to greater than $5,000 U.S. dollars?**

*Because PHS regulations do not exclude income from authorship activities, you must include them in your response to this question. Please do not include royalties or other payments on intellectual property rights in your response to this question.*

**NO \_\_\_\_ YES \_\_\_\_** If yes, complete table below

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Entity** | **Type of Business** | **Amount in U.S. Dollars** | **Activity** | **Individual Receiving Remuneration:****You/Spouse/Dependent Children** |
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**(b) During the past 12 months, did you, your spouse or your dependent children hold ANY equity interests in any non-publicly traded entity that is, or would appear, to be reasonably related to your organizational responsibilities?**

**NO \_\_\_\_ YES \_\_\_\_** If yes, complete table below

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Entity** | **Type of Business** | **Type of Equity** | **Value in U.S. Dollars** | **Individual Holding the Equity: You/Spouse/Dependent Children** |
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**3. During the past 12 months, did you, your spouse or your dependent children receive any *remuneration* from a non-profit *entity* that is, or would appear, to be reasonably related to your organizational responsibilities and that when combined amounted to greater than $5,000 U.S. dollars?**

 *Because PHS regulations do not exclude income for authorship activities or income from external professional organizations, you must include them in your response to this question. Also in accordance with PHS regulations, you must include income from a foreign institution of higher education or the government of another country in your response to this question.*

**Do not include the following:**

* Income from seminars, lectures and teaching engagements sponsored by U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education;
* Income from service on advisory committees or review panels for U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals and U.S. medical centers that are affiliated with U.S. Institutions of higher education; and
* Royalties or other payments on intellectual property rights in your response to this question.

**NO \_\_\_\_ YES \_\_\_\_** If yes, complete table below

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Entity** | **Amount in U.S. Dollars** | **Activity** | **Individual Receiving Remuneration: You/Spouse/Dependent Children** |
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**4. During the past 12 months, did a third party pay for greater than $5,000 (U.S. dollars) of travel for you, your spouse or your dependent children related to your responsibilities at the University of Guelph?**  *For the purposes of this disclosure, travel costs are those that exceed $5,000 U.S. dollars (either for one trip or a combination of trips from a single entity). Travel costs include meals, transportation, lodging, and registration fees.*

Third party paid travel means:

* Third party directly pays in whole or in part for travel on your behalf;
* You pay for travel and third party reimburses you in whole or in part; and/or
* University of Guelph pays in whole or in part for travel and the third party reimburses University of Guelph

PHS regulations **include** travel paid by:

* For profit entities;
* Non-profit entities including external processional organizations and societies
* Academic journals and publishing companies; and
* A foreign institution of higher education or the government of another country.

PHS regulations **exclude** travel paid by:

* Subrecipient Organization;
* U.S. Federal, state or local government agencies;
* U.S. Institutions of higher education or U.S. research institutes; and
* U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education.

**NO** \_\_\_\_ **YES** \_\_\_\_ If yes, complete table below

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Destination** | **Duration of Trip** | **Estimated Value in U.S. Dollars** | **Purpose** | **Sponsor/Organizer Who Paid for the Travel** |
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**5. During the past 12 months did you, your spouse, or your dependent children have any income greater than $5,000 for intellectual property rights (e.g., patents, patent applications, license agreements, or copyrights) resulting from or related to your work at, but not owned by, the University of Guelph?**

*Do not include payments from or intellectual property owned by the University of Guelph*

**NO**  \_\_\_\_ **YES** \_\_\_\_ If yes, complete table below

|  |  |  |
| --- | --- | --- |
| **Short Description of Invention/IP** | **Is it Licensed/Patented/Patent Pending?** | **If receiving royalties/other payments indicate the name of the entity providing the royalty/payment.** |
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**Certification:**

I certify that I have read and understand the document entitled University of Guelph Responsibilities Regarding Financial Conflict of Interest When Applying For or Receiving Funding from U.S. Public Health Service Agencies and have completed this Significant Financial Interest Disclosure Form to the best of my knowledge and belief. Further, as someone who is identified as an Investigator on a PHS proposal/award, subaward, or non-federal sponsor adopting the Public Health Services (PHS) regulations, I agree to comply with PHS regulatory requirements set out in said document as well as acknowledge the following:

* No later than at the time of proposal/application I will ensure that a current financial interest disclosure is on file;
* I will fulfill my disclosure responsibilities at least annually or within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest during the period of the award whichever comes first, including the occurrence of any reimbursed or sponsored travel which is paid on my behalf, related to my responsibilities at the University of Guelph;
* If I fail to report a new significant financial interest within 30 days, I will willingly participate in the required retrospective review of my research in order to determine bias;
* I will comply with the decisions of University of Guelph Designated Officials reflected in a management plan, if one is issued;
* If I am a Principal Investigator, I will appropriately identify in my proposal any individuals (i.e.,” Investigators”) who are responsible for the conduct, design, or reporting of the research. I will take into consideration the role of the investigator, rather than their title and the degree of independence with which the investigator will work;
* That University of Guelph must comply with written requests for information regarding my reported financial conflict of interests. University of Guelph’s response must be within 5 business days and will include:
	+ My name;
	+ My title and role with respect to the research project;
	+ The name of the entity in which the significant financial interest is held;
	+ The nature of the significant financial interest; and
	+ The approximate dollar value of the significant financial interest will be provided in the following dollar ranges: $0–$4,999; $5,000–$9,999; $5,000–$19,999; amounts between $20,000–$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), 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; and
* That the University of Guelph may impose sanctions on me if I fail to comply with the PHS regulations and the Investigator responsibilities set out in the document entitled University of Guelph Process Responsibilities When Applying For or Receiving Funding From U.S. Public Health Service Agencies.

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