

 DALHOUSIE UNIVERSITY <i>Inspiring Minds</i>	<i>Martha Crago</i> <i>Policy Sponsor:</i> Vice President Research	<i>July 22/2013</i> <i>Approval Date:</i>
	US Public Health Service Financial Conflict of Interest Policy	<i>Responsible Unit:</i> Research Services

A. Background & Purpose

In 2012, the U.S. Public Health Service (“PHS”) amended its Financial Conflict of Interest requirements under its *Regulation on the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought*. This regulation is intended to promote objectivity in research by establishing standards to provide a reasonable expectation that if an investigator has Financial Conflict of Interest, it will not influence the design, conduct and reporting of research funded by the PHS.

The purpose of this Policy is to provide direction to members of the Dalhousie University community who apply for or are engaged in PHS funded research and to assist them in meeting the requirements of the PHS regulations.

B. Application

This Policy applies to PHS-funded research and to those who apply for PHS funding.

C. Definitions

1. In this Policy:
 - a. “Designated Official” means the person employed or appointed by the Vice-President Research who is responsible to administer this Policy.
 - b. “Disclosure” means an Investigator’s disclosure of Significant Financial Interests to Dalhousie University.
 - c. “Equity Interest” means any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - d. “Financial Conflict of Interest” means a Significant Financial Interest that could reasonably be perceived to directly and significantly affect the design, conduct or reporting of a PHS-funded research project.
 - e. “Financial Interest” means anything of monetary value, whether or not the value is readily ascertainable.

- f. "Investigator" means the Project Director, Principal Investigator, Senior or Key Personnel identified as such in any report submitted to the PHS by Dalhousie, collaborators or consultants, or any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research funded by or proposed to be funded by PHS components.
- g. "Manage" means taking action to address a Financial Conflict of Interest under section F.3. of this Policy, which can include reducing or eliminating the Financial Conflict of Interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- h. "Management Plan" means Dalhousie's internal report under section F.3. of this Policy regarding identified Financial Conflicts of Interest and how those conflicts are being managed, mitigated or eliminated.
- i. "PHS" means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS, including but not limited to, the National Institutes of Health.
- j. "Senior/Key Personnel" means the Project Director, Principal Investigator and any other person identified as senior/key personnel by Dalhousie in the grant application, progress report, or any other report submitted to the PHS by Dalhousie.
- k. "Significant Financial Interest" means a Financial Interest of an Investigator, or his or her spouse or dependent children, received in the 12 months preceding an Investigator's Disclosure, that reasonably appears to be related to the Investigator's University Responsibilities and includes:
 - i. Remuneration from a publicly traded entity (received in the 12 months preceding an Investigator's Disclosure) plus the value of any Equity Interest in that entity that exists on the date of the Disclosure that exceeds \$5,000;
 - ii. Remuneration from a non-publicly traded entity that exceeds \$5,000 or when the Investigator holds any Equity Interest in that entity;
 - iii. Remuneration for intellectual property rights and interests that exceeds \$5,000;
 - iv. All reimbursed or sponsored travel that exceeds \$5,000 which is related to the Investigator's University Responsibilities that is paid for by a body other than a U.S. federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical centre or U.S. research institute affiliated with a U.S. institution of higher education.

Significant Financial Interest does not include:

- v. Salary, royalties or other remuneration (including for travel) paid by Dalhousie, if the Investigator is employed by or otherwise appointed to Dalhousie;
- vi. Intellectual property rights and interests assigned to Dalhousie;
- vii. 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;
- viii. Income from seminars, lectures or teaching engagements sponsored by, or service on advisory or review committees for, a U.S. federal, state, or local government agency, a

U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical centre or U.S. research institute affiliated with a U.S. institution of higher education.

- I. "University Responsibilities" means professional responsibilities that an Investigator performs on behalf of Dalhousie including, but not limited to, research, research consultation, teaching/education, professional practice and University committee memberships.

D. Policy

1. All Investigators shall follow the procedures of this Policy regarding disclosing Significant Financial Interests, following applicable Management Plans and engaging in Financial Conflict of Interest training.
2. If Dalhousie undertakes PHS-funded research through or with a subrecipient, the Designated Official shall take reasonable steps to ensure that any subrecipient Investigator complies with PHS regulations.
3. Persons engaged in PHS-funded research shall cooperate in any duly authorized inspection or audit activities of the PHS.
4. Access to information requests regarding identified Financial Conflict of Interests of Senior/Key Personnel shall be dealt with in accordance with the Procedures.
5. Failure to follow this Policy may result in the suspension of financial activity in an Investigator's research account and/or the termination of PHS research funding.
6. This Policy applies in addition to, and not in place of, the Dalhousie Policy on Conflict of Interest.

E. Administrative Structure

1. Authority: This Policy falls under the authority of the Vice-President Research.
2. Designated Official: The Designated Official shall administer the procedures under this Policy.
3. Record-keeping: Records regarding all aspects of this Policy, including supporting documentation, will be maintained and stored securely and confidentially under the care and control of the Designated Official. All records regarding this Policy must be retained for at least 3 years from the date the final expenditure report is submitted to PHS or the date of final payment by the PHS, whichever is later, or for any other time period specified by the PHS.

F. Procedures

1. Investigator Disclosure:
 - a. Principal Investigators and Project Directors shall advise the Designated Official of all Investigators and/or consultants who share in the responsibility for the design, conduct and reporting of PHS-funded research.

- b. Principal Investigators and Project Directors shall advise all Investigators assigned to their PHS-funded research of their obligations under this Policy.
 - c. All Investigators applying for PHS funding shall submit a completed Significant Financial Interest Disclosure Form (Appendix A) to the Designated Official at least 30 days prior to submitting any PHS funding application.
 - d. All Investigators holding PHS funds shall submit a completed Significant Financial Interest Disclosure Form (Appendix A) to the Designated Official on an annual basis and within 30 days of any new Significant Financial Interest being discovered or acquired.
 - e. If Dalhousie engages a subrecipient in PHS-funded research, the Designated Official shall ensure the written agreement with the subrecipient confirms whether this Policy or the subrecipient's Financial Conflict of Interest policy applies to the subrecipient's Investigators. If the subrecipient's Financial Conflict of Interest policy applies, the Designated Official shall take reasonable steps to ensure that policy complies with the PHS regulation. If this Policy applies, the Designated Official shall ensure a written agreement with the subrecipient confirms its Investigator Disclosure requirements.
2. Determination of a Financial Conflict of Interest: The Designated Official shall assess all Significant Financial Interest Disclosures and determine:
- a. whether a Significant Financial Interest is related to PHS research. A Significant Financial Interest is related to PHS-Funded research if the Designated Official reasonably determines that a Significant Financial Interest could be affected by the PHS-funded research or the Significant Financial Interest is in an entity whose financial interest could be affected by the PHS-funded research; and
 - b. if so, whether it amounts to a Financial Conflict of Interest. A Financial Conflict of Interest exists if the Designated Official reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the PHS-funded research.
3. Managing a Financial Conflict of Interest: If the Designated Official determines that a Financial Conflict of Interest exists, the Designated Official shall develop and implement a Management Plan that shall include:
- a. The role and principal duties of the conflicted Investigator in the research project;
 - b. The actions that have been taken and that will be taken to Manage the conflict. These may include, but are not limited to:
 - i. Notifying colleagues of the Financial Conflict of Interest; public disclosure of Financial Conflict of Interest (e.g., when presenting or publishing research);
 - ii. Disclosing Financial Conflict of Interest s directly to research participants;
 - iii. Appointing an independent person to monitor the research;
 - iv. Modifying the research plan;

- v. Changing responsibilities or disqualifying individuals from participation in all or a portion of the research;
 - vi. Reducing or eliminating the financial interest; or
 - vii. Severing relationships that create a Financial Conflict of Interest
- c. Confirmation of the Investigator's agreement to the Management Plan;
 - d. How the Management Plan will be monitored to ensure Investigator compliance; and
 - e. Other information as required by the Designated Official.
4. PHS Reporting requirements: The Designated Official shall provide Financial Conflict of Interest reports to the appropriate PHS component that include sufficient information to enable PHS to understand the nature and extent of the financial conflict, and to assess the appropriateness of Dalhousie's Management Plan. Financial Conflict of Interest reports must be provided to PHS for the duration of the research project at the following times:
- a. After the award is granted but prior to the University's expenditure of any funds;
 - b. Within 60 days of any subsequently identified Financial Conflict of Interest;
 - c. On an annual basis; and
 - d. At any other time specified by PHS.
5. Training: The Designated Official shall ensure appropriate Financial Conflict of Interest training is available. All Investigators shall complete this training and submit a certificate of completion to the Designated Official prior to engaging in any PHS funded research, at least every four years thereafter and immediately when:
- a. This Policy changes in a manner that affects Investigator requirements; or
 - b. An Investigator is noncompliant with this Policy.
6. Investigator Noncompliance: Investigators found to be noncompliant with these procedures will be required to undergo a retrospective review of their Significant Financial Interests and will be required to disclose their Financial Conflicts of Interest in each public presentation of the results of research and to request an addendum to previously published presentations.
7. Access to Information: Within 5 business days of a request from any member of the public for information regarding identified Financial Conflicts of Interest held by Senior/Key Personnel, the Designated Official will provide: the investigator's name, title and role with respect to the research project; the nature of the Significant Financial Interest; the entity with which the investigator has an Financial Conflict of Interest; and the approximate dollar value of the Significant Financial Interest or a statement that a value cannot be readily determined.

APPENDIX A: Significant Financial Interest Disclosure Form

Submitted pursuant to the US Public Health Service
Regulation on the Responsibility of Applicants for Promoting Objectivity in Research respecting
Financial Conflicts of Interest (FCOI)

Name: _____
 Department: _____
 Faculty: _____
 Title of Grant: _____

Type of Award/Grant:

I am reporting on activities: for the year _____
 as an addendum to my most recent report

Declarations:

<input type="checkbox"/> yes	<input type="checkbox"/> no	<p>1. Financial Interests: Have you, your spouse or dependent children (your “Family”) received in the past 12 months anything of monetary value including salary or other payments for services (e.g. consulting payments, director fees, honoraria, royalties or other payments for patents or copyrights) from an Entity exceeding \$5,000 that would reasonably appear to be related to your University responsibilities?</p> <p><i>Exemption:</i> Do not include:</p> <ul style="list-style-type: none"> • any remuneration from Dalhousie University • income from seminars, lectures or teaching engagements sponsored by, and service on advisory or review panels for, a U.S. federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical centre or U.S. research institute affiliated with a U.S. institution of higher education • income from investment vehicles, such as mutual funds and retirement accounts, so long as you or your Family do not directly control the investment decisions made in these vehicles
<input type="checkbox"/> yes	<input type="checkbox"/> no	<p>2. Equity Interests: Do you or a member of your Family:</p> <p>a) own stock, stock options or other ownership interests with a monetary value exceeding \$5,000 from a publicly-traded entity where such interests would reasonably appear to be related to your University responsibilities? <i>(For stock in non-publicly traded entities, use the most recent sales price recognized by the Entity.)</i></p> <p>b) own an equity interest in any single Entity where its value could be affected in any way as a result of your University responsibilities?</p> <p>If yes to 2a and/or 2b, provide information on the nature of these interests on a separate page.</p> <p><i>Exemption:</i> Do not include equity interests in investment vehicles, such as mutual funds and retirement accounts, so long as you or your Family do not directly control the investment decisions made in these vehicles.</p>
<input type="checkbox"/> yes	<input type="checkbox"/> no	

APPENDIX A: Significant Financial Interest Disclosure Form

Submitted pursuant to the US Public Health Service
Regulation on the Responsibility of Applicants for Promoting Objectivity in Research respecting
Financial Conflicts of Interest (FCOI)

<input type="checkbox"/> yes	<input type="checkbox"/> no	<p>3. Intellectual Property: Have you or your Family received remuneration exceeding \$5,000 from any Entity in relation to your intellectual property rights and interests in the past 12 months?</p> <p>Exemption: Do not include any remuneration from Dalhousie University.</p>
<input type="checkbox"/> yes	<input type="checkbox"/> no	<p>4. Travel: Has any Entity reimbursed travel or sponsored travel for you or your Family exceeding \$5,000 that would reasonably appear to be related to your University responsibilities?</p> <p><i>Exemption: Do not include:</i></p> <ul style="list-style-type: none"> • travel that is reimbursed by Dalhousie University. • travel that is reimbursed by a U.S. federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical centre or U.S. research institute affiliated with a U.S. institution of higher education.

****If you have responded “Yes” to any of the above, please provide additional information as indicated on the following page (Page 3).****

I have read and understand Dalhousie University’s Financial Conflict of Interest Policy and have completed this report to the best of knowledge and belief. I understand that completing and signing this Declaration does not exempt me from any other requirements determined by any PHS component or from any other University policies and procedures. Should my outside financial interests, or those of my family, change in a way that results in different answers to any of the questions asked in this report, I agree to submit a revision.

 (date)

 (signature)

APPENDIX A: Significant Financial Interest Disclosure Form

Submitted pursuant to the US Public Health Service
Regulation on the Responsibility of Applicants for Promoting Objectivity in Research respecting
Financial Conflicts of Interest (FCOI)

Addition to Financial Interests Report of: _____

Reporting for self family member

name: _____

relationship: _____

Name of External Entity: _____

Address of External Entity: _____

Type of external relationship: (check all that apply)

<input type="checkbox"/>	Consultant
<input type="checkbox"/>	Speaker
<input type="checkbox"/>	Advisory Board or Committee
<input type="checkbox"/>	Equity Holdings
<input type="checkbox"/>	Governing Board or Officer
<input type="checkbox"/>	Intellectual Property Rights
<input type="checkbox"/>	Royalty Income
<input type="checkbox"/>	Other (describe below)

Amount of compensation or financial interest in reporting period: \$ _____

If travel paid by Entity:

Destination _____

Amount \$ _____

Comments or explanatory information (*attach additional page(s) as necessary*)

APPENDIX A: Significant Financial Interest Disclosure Form

Submitted pursuant to the US Public Health Service
Regulation on the Responsibility of Applicants for Promoting Objectivity in Research respecting
Financial Conflicts of Interest (FCOI)

Dalhousie University Research Services Use Only

I _____ have reviewed this financial interests form and have determined that the significant financial interests (SFI) reported do not represent a financial conflict of interest (FCOI) as it relates to this PHS funding.

Signature of Designated Official

Date