



U.S. Public Health Service (PHS) Funding Investigator Requirements and Disclosure Form Concerning Financial Conflict of Interest

For Investigators submitting, holding or taking part in a U.S. Public Health Service (PHS) Grant or Contract

Introduction:

The U.S. PHS has rules that must be followed with respect to PHS funded research and Investigator financial conflict of interest. For the purposes of these procedures, "Investigator" is defined 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 PHS funded research, or proposed for such funding, which may include, for example, collaborators or consultants. Investigator also includes Senior/key personnel identified as such by the University in the grant application, progress report, or any other report submitted to PHS by the University under this Procedure. Agencies which fall under PHS regulations are shown on page 2 of this document.

All Investigators must disclose conflicts of interest (for themselves and their family) related to institutional responsibilities to the University. They must also certify in their grant application that they have done so (and will continue to do so during the period of the award) and that they will comply with the conditions or restrictions imposed by the University for managing, reducing or eliminating the conflict of interest. Please consult the [full regulations](#) as well as [McMaster's Institutional Procedure for compliance with the U.S. PHS Financial Conflict of Interest \(FCOI\)](#) for more details. Please complete the declaration and disclosure sections of this document, found on pages 3 to 6, and submit a signed copy to the appropriate Faculty contact listed below.

Applicability:

To be in compliance with these requirements, **all Investigators** applying for or holding U.S. PHS funding must sign and submit this declaration and disclosure form (pages 3-6):

- a. at the time of application for PHS-funded research, and
- b. at least annually during the period of the award, and
- c. within 30 days of discovering or acquiring a new significant financial interest, and
- d. upon request by the University (during the period of the award)

Apparent significant non-compliance (or with the University determinations for managing, reducing, or eliminating the conflict of interest) may result in sanctions by the University and/or the PHS.

Confidentiality:

All information contained in this declaration and disclosure form and provided to McMaster University by Investigators shall be kept private and confidential, to the extent allowed by law.

Addressing Significant Conflicts:

Examples of conditions or restrictions that might be imposed (i.e. Strategies for managing, reducing or eliminating the conflict of interest) have been articulated in the PHS rules and include, but are not limited to: public disclosure of the significant financial interests; monitoring of the research by independent reviewers; modification of the research plan; disqualification from participation in all or a portion of the research funded by the PHS; divestiture of significant financial interests; or severance of relationships that create actual or potential conflicts.

Certification:

To demonstrate your compliance with the requirements of the PHS, you are required to complete an [online FCOI tutorial](#) on the NIH OER website. This training is required every four years. Upon completion of the tutorial, please submit your completed tutorial certificate and Declaration and Disclosure forms to the appropriate Faculty contact listed below.

SUBMIT TO:

For the Faculty of Health Sciences: hsresadm@mcmaster.ca

For all other Faculties: Helen Bartens, bartensh@mcmaster.ca

List of PHS Agencies:

- U.S. Department of Health and Human Services
 - Administration for Children and Families (ACF)
 - Administration on Children, Youth and Families (ACYF)
 - Administration for Community Living (ACL)
 - Administration on Aging
 - Agency for Healthcare Research and Quality (AHRQ)
 - Agency for Toxic Substances and Disease Registry (ATSDR)
 - Centers for Disease Control and Prevention (CDC)
 - Centers for Medicare & Medicaid Services
 - Federal Occupational Health
 - Food and Drug Administration (FDA)
 - Health Resources and Services Administration (HRSA)
 - Indian Health Service (IHS)
 - NIH – National Institutes of Health
 - National Cancer Institute (NCI)
 - National Eye Institute (NEI)
 - National Heart, Lung, and Blood Institute (NHLBI)
 - National Human Genome Research Institute (NHGRI)
 - National Institute on Aging (NIA)
 - National Institute on Alcohol Abuse and Alcoholism (NIAAA)
 - National Institute of Allergy and Infectious Diseases (NIAID)
 - National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
 - National Institute of Biomedical Imaging and Bioengineering (NIBIB)
 - *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
 - National Institute on Deafness and Other Communication Disorders (NIDCD)
 - National Institute of Dental and Craniofacial Research (NIDCR)
 - National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
 - National Institute on Drug Abuse (NIDA)
 - National Institute of Environmental Health Sciences (NIEHS)
 - National Institute of General Medical Sciences (NIGMS)
 - National Institute of Mental Health (NIMH)
 - National Institute on Minority Health and Health Disparities (NIMHD)
 - National Institute of Neurological Disorders and Stroke (NINDS)
 - National Institute of Nursing Research (NINR)
 - National Library of Medicine (NLM)
 - Center for Information Technology (CIT)
 - Center for Scientific Review (CSR)
 - John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC)
 - National Center for Complementary and Alternative Medicine (NCCAM)
 - National Center for Advancing Translational Sciences (NCATS)
 - NIH Clinical Center (CC)
 - Office of the Assistant Secretary for Health (OASH)
 - Office of the Assistant Secretary for Preparedness and Response (ASPR)
 - Office of Global Affairs (OG)
 - Substance Abuse and Mental Health Services Administration (SAMHSA)

Organizations following PHS regulation:

- Alliance for Lupus Research
- Alpha-I Foundation
- American Asthma Foundation
- American Cancer Society (ACS)
- American Heart Association (AHA)
- American Lung Association (ALA)
- Arthritis Foundation (AF)
- Cure PSP
- Juvenile Diabetes Research Foundation (JDRF)
- Lupus Foundation of American (LFA)
- Patient-Centered Outcomes Research Institute (PCORI)
- Susan G. Komen Foundation

PART 1 – DECLARATION AND DISCLOSURE

Investigator Information:

Name: _____ Title: _____
Department: _____ Name of PI: _____
Title of Grant or Contract: _____
Duration of Grant or Contract: _____
Sponsor: _____

Declaration:

I Agree to comply with the requirements of the “U.S. Public Health Service (PHS) Funding Requirements and Disclosure Form Concerning Financial Conflict of Interest”.

I acknowledge that I have read McMaster’s Institutional Procedure for compliance with the U.S. PHS Financial Conflict of Interest (FCOI) and agree to comply with the Procedure.

I have completed the [online FCOI tutorial](#) on the NIH OER website and submitted a copy of the certificate of completion to the appropriate grant officer.

I understand that completing and signing this declaration and disclosure form does not exempt me from any other requirements determined by the PHS (as applicable), requirements as part of the PHS submission or from any University policies or procedures.

Signature: _____ Date: _____

Disclosure (Part I) Answer each question. Family means spouse/domestic partner and dependent children.

Is this disclosure being made (please check one):

At time of Grant Submission As an Annual Disclosure
As a New Reportable Interest At the Request of University

1. Financial Interests Yes No

From any entity, have you received in the last twelve months or do you expect to receive in the next twelve months, anything of monetary value including salary or other payments for service (e.g., director’s fees, reimbursed or sponsored travel, consulting payments, honoraria, royalties or other payments for patents or copyrights) in excess of \$5,000? (Aggregate for yourself and your family)?

Note: Do not include salary and royalties or other remuneration from McMaster University, income from seminars, lectures, or teaching engagement sponsored by public or non-profit entities, or income from service on advisory committees or review panels for public or non-profit entities. Do not include royalties from books and manuscripts. Do not include travel that is 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.

2. Equity Interests

Do you have or anticipate having stock, stock options or other ownership interests with a monetary value in excess in \$5,000 (fair market value) (aggregate for yourself and your family)? For stock in companies not publicly traded, use the most recent sales price recognized by the company.

Yes No

3. Other Financial Interests

Do you or your family have or will have a financial interest not already reported in this disclosure?

Yes

No

I certify that this is a complete disclosure of all financial interests related to my institutional responsibilities:

Signature: _____

Date: _____

**If you answered "YES" to ANY of the above questions, please complete Part II
(Significant Financial Disclosure).**

If you answered "NO" to ALL of the above questions, your disclosure is complete.

**Please complete this Declaration and Disclosure Form annually during the period of your grant or
contract, thank you!**

Disclosure (Part II – Significant Financial Disclosure)

Instructions: Complete Part II only if you answered “YES” to ANY question in Part I. Submit one form for each entity for which there was a “Yes” in Part I. Family means spouse/domestic partner and dependent children.

Institutional Personnel Information:

Name: _____ Title: _____
Department: _____ Name of PI: _____
Title of Grant or Contract: _____
Duration of Grant or Contract: _____
Sponsor _____
Number of Forms Submitted: _____

Is this disclosure being made (please select one):

- At time of Grant Submission As an Annual Disclosure
As a New Reportable Interest At the Request of University

1. Name of Entity (Company, public or non-profit organization):

2. Share Ownership (if a company): Public Private

3. Value of Financial Interest per year (please specify USD or CAD):

4. Financial Connection with the Entity: (check ALL that apply)

- Consulting Director, Officer, Partner, Agent, or Managerial Position
 Employment Royalties
 Loan Dividends
 Gifts Spouse is employee
 Honoraria Other (Please Specify):

5. From *this* entity, have you received in the last twelve months or do you expect to receive in the next twelve months – salary or other payments for service (e.g., director’s fees, reimbursed or sponsored travel, consulting payments, honoraria, royalties or other payments for patents or copyrights) in excess of \$5,000? (Aggregate for yourself and your family)

Yes No

6. For *this* entity, do you have or anticipate having stock, stock options or other ownership interests of significant monetary value in excess of \$5,000 (fair market value) (Aggregate for yourself and your family). For stock in companies not publicly traded, use the most recent sales price recognized by the company.

Yes No

7. Does the entity have a relationship with McMaster University (e.g., research sponsor, consortium member, vendor, etc.)?

Yes No

If yes, please describe the relationship briefly:

8. In your judgment, could your financial interest or the financial interests of the entity reasonable appear to be affected by your PHS research?

Yes No

Please provide a brief justification for your opinion:

I certify that this is a complete disclosure of all financial interests related to this Entity:

Name: _____

Title: _____

Department _____

Signature _____ Date: _____