



**POLYTECHNIQUE
MONTREAL**

UNIVERSITÉ
D'INGÉNIERIE

**Translation of an official document
circulated by the Secretary General**

Regulations governing Financial Conflicts of Interest of United States of America's Public Health Services sponsored investigators

ADOPTION (COMMITTEE/AUTHORITY)	DATE	RESOLUTION
Conseil d'administration	2021-05-27	CAD-1115-5692

AMENDMENT(S) AND ADJUSTMENT(S)		

CLASSIFICATION	Recherche et innovation
COTE	R-RECH-01
ENTRY INTO FORCE	2021-05-27
RESPONSIBLE FOR APPLICATION	Directrice ou directeur de la formation et de la recherche

HISTORY
DISCLAIMER: This document is an informative tool only. In the event of any discrepancy between this document and the French version of this Policy, the latter takes precedence.
The official version of this document is available here: Règlement régissant les conflits d'intérêts financiers chercheuses et chercheurs - version française Version 2021-05-27

TABLE OF CONTENTS

1	INTRODUCTION.....	3
2	SCOPE.....	3
3	LEGAL FRAMEWORK.....	3
4	DEFINITIONS.....	4
5	PROCEDURES FOR HANDLING FCOI.....	6
5.1	Disclosure of financier interests	6
5.1.1	Annual disclosure	6
5.1.2	Ad hoc disclosure	6
5.1.3	Travel.....	6
5.2	Review and decision of the institutional official	7
5.3	Review of significant financial interests related to clinical trials.....	7
5.4	Reporting to PHS.....	7
5.5	Investigator non-compliance	8
5.5.1	Disciplinary Action.....	8
5.5.2	Retrospective Review.....	8
5.6	Training.....	8
5.7	Record retention.....	9
5.8	Confidentiality	9
5.9	Public accessibility.....	9
5.10	Regulatory authority.....	9
6	FUNCTIONAL STRUCTURE.....	10
7	SANCTIONS.....	10
8	FINAL PROVISIONS	10
8.1	Minor changes.....	10

1 INTRODUCTION

National Institutes of Health require recipient institutions¹ and investigators comply with the requirements of 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" (FCOI Regulation), as implemented in the 2011 Final Rule for grants and cooperative agreements.

These requirements promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from any conflicting financial interest of an Investigator.

Polytechnique shall maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with the above regulation and will make the policy available via a publicly accessible website.

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the Institution to manage conflicts of interest that arise, and describes situations that are prohibited.

2 SCOPE

This policy governing Financial Conflict of Interest applies to all PHS-sponsored Investigators of Polytechnique.

3 LEGAL FRAMEWORK

The legal framework for this regulation is:

- *42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" (FCOI Regulation)*
- *45 CFR Part 94 "Responsible Prospective Contractors".*

A number of Polytechnique's institutional policies, procedures and rules may also apply, including:

- *the Probity Policy;*
- *the Politique sur l'administration des fonds de recherche (policy on the administration of research funds);*
- *the Politique sur les relations avec les entreprises dérivées (policy on relations with related businesses);*

¹ In the United States of America, as of the writing of the current policy, these agencies/organizations comprise: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), Substance Abuse and Mental Health Services Administration (SAMHSA). Please see current policy text for selected Canadian equivalents.

- *the Policy on the Ethical Conduct of Research Involving Human Subjects;*
- *the Procedure for the Certification of Research Projects Involving Biohazards;*
- *the Procedure for the Ethical Certification of Research Projects Involving Animals;*
- *the Règlement sur les conflits d'intérêts des membres du personnel (regulation on conflicts of interest among staff);*

The policies and rules of granting agencies, both federal (NSERC, SSHRC, CIHR, CFI, etc.) and provincial (FQRNT, FQRSC, FRSQ, etc.), may also apply.

4 DEFINITIONS

“Clinical Trial” means any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices, or medical or other clinical procedures, such as surgery.

“Conflict of Interest Committee” (COI Committee) means the Responsible conduct of research officer (e.g. the individual that advises the Institutional Official on conflict of interest matters.) The Responsible conduct of research officer can convene a committee consisting of three members, namely, the external examiner (who acts as the committee chair) and whom is from outside the Polytechnique community, and two other impartial members from the Polytechnique community who are not in a conflict of interest vis à vis either party connected to the allegation. This committee is not mandated to investigate, but rather to assess the situation and determine whether to proceed to a formal investigation.

“Family” means any member of the Investigator’s immediate family, specifically, any dependent children and/or spouse.

“Financial Interest” means anything of monetary value received or held by an Investigator or an Investigator’s Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from Polytechnique;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to their institutional responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies,

U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

“Significant Financial Interest” means a Financial Interest that reasonably appears to be related to the Investigator’s Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds US\$ 5,000, or the equivalent in Canadian dollars depending on the exchange rate; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds US\$ 5,000, or the equivalent in Canadian dollars depending on the exchange rate; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure; or
- d) is income exceeding US\$ 5,000, or the equivalent in Canadian dollars depending on the exchange rate, related to intellectual property rights and interests not reimbursed through Polytechnique, or
- e) is reimbursed or sponsored travel related to their Polytechnique-related responsibilities.

“Financial Conflict of Interest” means a Significant Financial Interest (or, where the Institutional Official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

“Institutional Official” means the individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator’s Family related to the Investigator’s institutional responsibilities. For the purposes of this policy, the Institutional Official is designated as *Responsible conduct of research officer*.

“Institutional responsibilities” means the Investigator’s professional responsibilities associated with their Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

“Investigator” means any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

“Public Health Service (PHS)” means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

“Research” means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

5 PROCEDURES FOR HANDLING FCOI

Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation that raises questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Official.

5.1 Disclosure of financier interests

All Investigators are required to disclose their outside financial interests as defined above to Polytechnique on an annual and on an ad hoc basis, as described below.

5.1.1 Annual disclosure

All Investigators must disclose their Significant Financial Interests that are related to the Investigator’s institutional responsibilities to Polytechnique, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional Official or designee by March 1 for the previous calendar year, or as determined by the subrecipient.

5.1.2 Ad hoc disclosure

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to Polytechnique, through the Institutional Official, within 30 days of their initial appointment or employment.

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the Institutional Official an ad hoc updated disclosure of their Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional Official an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

5.1.3 Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is required (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator’s research.

5.2 Review and decision of the institutional official

If the Disclosure Form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee to determine whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to manage the Financial Conflict of Interest including the reduction or elimination of the conflict, as appropriate. The Institutional Official may consult the COI Committee for guidance in specific cases, or for the application of the policy to particular situations.

A Financial Conflict of Interest exists when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, they must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

The Institutional Official will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of research results, and to otherwise oversee compliance with the management plan.

5.3 Review of significant financial interests related to clinical trials

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.

- a) In accordance to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018), article 7.4, Investigators shall disclose in research proposals they submit to the Research Ethics Board (REB)² any real, potential or perceived individual conflicts of interest, as well as any institutional conflicts of interest or community conflicts of interest of which they are aware, that may have an impact on research. Upon discussion with the researcher, the REB shall determine the appropriate steps to manage the conflict of interest.
- b) In the event of non-compliance with reporting and/or management of a Financial Conflict of Interest involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this Policy, the Investigator must disclose the financial conflicts of interest in each public presentation of the results of the affected PHS-sponsored research and request an addendum to previously published presentations.

5.4 Reporting to PHS

The Institutional Official will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations. If research funding is made available from a principal PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified Financial Conflict of Interest such that the principal awardee may fulfill their reporting obligations to the PHS.

² The *Comité d'éthique de la recherche* (CER)/Research Ethics Board (REB) is the Canadian equivalent of the U.S. body the *Institutional Review Board* (IRB).

5.5 Investigator non-compliance

5.5.1 Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented. In particular, the Institutional Official may freeze grant accounts, require a second authorized signature (that of a representative of the institution) for all expenses charged to the researcher's grant accounts, or take other measures, as the case may be, until the issue is resolved or other measures deemed appropriate by the COI Committee, if the circumstances so warrant, are implemented in accordance with the practices and regulations in force at Polytechnique.

All measures imposed by an Institutional Official upon an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision communicated to the Investigator, and, where applicable, the Research Ethics Board – REB. The Institutional Official will notify the individual of the right to appeal the decision by following the *Règlement sur les conflits d'intérêts des membres du personnel*. Polytechnique will promptly notify the PHS Awarding Component of the action taken or to be taken. If the research funding is made available from a principal PHS awardee, such notification shall be made promptly to the principal awardee for reporting to PHS.

5.5.2 Retrospective Review

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a committee appointed by the Institutional Official will complete a retrospective review of the Investigator's activities and the PHS-sponsored research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of said research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official will update any previously submitted report relating to the research to the PHS or the principal PHS-awardee, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner set out by and within the time frame established in PHS regulations. If bias is found, Polytechnique will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, contain a description of the impact of the bias on the research project, and include a plan of action to eliminate or mitigate the effect of the bias.

5.6 Training

Each Investigator must complete training about this Policy, about their responsibilities as investigator regarding disclosure, and about PHS regulations, prior to engaging in research funded by PHS. Training must be re-completed at least every four years thereafter. Investigators must also complete training within a reasonable period of time as determined by the Institutional Official in

the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the Investigator is new to Polytechnique, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

Each Investigator must send their completed training certificate to the Institutional Official so that the Institutional Official can enter it in their file.

5.7 Record retention

The Institutional Official will retain all disclosure forms, conflict of interest management plans, and related documents for a period of seven years from the date the final expenditure report is submitted to the PHS or to the principal PHS awardee. The latter, unless any litigation, claim, financial management review, or audit is started before the expiration of the seven year period, upon which the records shall be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken.

5.8 Confidentiality

To the extent permitted by law, all disclosure forms, conflict of interest management plans, and related information will remain confidential. However, Polytechnique may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning Financial Conflict of Interest related to PHS funding or to the primary entity who made the funding available Polytechnique, if requested or required. If Polytechnique is requested to provide disclosure forms, conflict of interest management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

5.9 Public accessibility

Prior to the expenditure of funds, Polytechnique will respond to any requestor according to the *Loi sur l'accès aux documents des organismes publics et sur la protection des renseignements personnels*³. Following the received request, information will be released that concerns any Significant Financial Interest that meets the following criteria:

- a) Significant Financial Interest was disclosed and is still held by senior and key personnel;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research;
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS regulation.

5.10 Regulatory authority

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, then the requirements shall take precedence.

³ English-language title of the Québec Government's act: *Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information*

6 FUNCTIONAL STRUCTURE

The Institutional Official shall ensure the implementation of these Rules, and may suspend all relevant activities until the Financial Conflict of Interest is resolved or other measures deemed appropriate are implemented.

The Institutional Official is responsible for the distribution, receipt, processing, review, and retention of reporting forms.

7 SANCTIONS

Violation of any part of these regulations may also give rise to disciplinary or other administrative measures in accordance with Polytechnique policies and regulations.

8 FINAL PROVISIONS

This Policy enters into effect at the moment of its adoption by the Conseil d'administration. It does not replace Polytechnique Montréal's other policies and guidelines, nor does it replace the terms of the collective agreements dealing with ethics or deontology. The terms of this Policy prevail in regard to research sponsored by PHS.

8.1 Minor changes

Any minor changes to this Policy may be made by the Responsible conduct of research officer and/or the Vice President responsible for the research, which informs the members of the *Assemblée de direction*.