

SUBJECT: POLICY ON CONFLICTS OF INTEREST OF THE CHUM RESEARCH DIRECTORATE (CRCHUM)	POLICY N° 50 401
ADDRESSED TO: Any person working at the CRCHUM or on behalf of a CRCHUM researcher	Issued on: June 11, 2012 Revised on: February 28, 2013 and April 14, 2015
ISSUED BY: Brigitte M Lespérance, Direction de la recherche (DR)	
APPROVED BY: Direction de la recherche (DR) and SIGNED BY: Vincent Poitout, Directeur de la recherche du CHUM et Directeur scientifique du CRCHUM	Date: April 14, 2015
<p>OBJECTIVE</p> <p>The purpose of this policy is to establish the standards applicable to persons concerned with conflicts of interest in the context of scientific research.</p> <p>1 SCOPE</p> <p>This policy applies to all individuals involved in research activities, including but not limited to: researchers (of all statuses), nurses, support staff, research assistants, students, post-doctoral, fellows, consultants, employees of researchers, employees and managers of the CHUM Research Centre.</p> <p>2 DEFINITIONS</p> <p><u>Conflict of interest:</u> A conflict of interest arises when activities or situations create a circumstance in which an individual or an institution has interests (personal, institutional or other) that are in conflict with their obligations and responsibilities associated with their role and functions. Such conflicts have the potential to distort decisions, erode from the public trust, the members of the CRCHUM, the stakeholders of the institution and its members.</p> <p><u>FCOI:</u> Financial Conflicts of Interest</p> <p><u>CRCHUM:</u> Research Center of the Centre Hospitalier de l'Université de Montréal / Research Directorate of the CHUM</p> <p><u>Institution :</u> Centre hospitalier de l'Université de Montréal (CHUM)</p> <p><u>SFI:</u> Significant financial interest(s)</p> <p><u>NIH:</u> National Institutes of Health (USA)</p>	

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PHS: Public Health Services (USA)

Policy: Policy on conflicts of interest of the CHUM Research Directorate – CRCHUM

Procedure: Procedure for declaring and handling conflicts of interest - CRCHUM

Relative(s): Includes the legal or de facto spouse, child, father, mother, brother and sister of a person, as well as the spouse and children of the above-mentioned persons, and a business partner.

DHHS rules: United States federal policy guidelines on disclosure of financial interests to promote objectivity in research (42 CFR Part 50 and 45 CFR Part 94).

3 POLICY STATEMENT

- 3.1** Individuals covered by this Policy may be placed in a real, potential or apparent situation of conflict of interest, in the course of their duties or research activities conducted in the CRCHUM or outside the CRCHUM.
- 3.2** In order to demonstrate transparency, integrity and to be in alignment with CRCHUM's values, and to comply with applicable laws and regulations, this Policy has been established to prevent, manage or resolve conflicts of interest arise during research-related activities, and to protect both individuals and the Institution.
- 3.3** This Policy requires individuals to avoid, whenever and disclose any activities that could create real, potential, or apparent conflicts of interest.
- 3.4** Individuals covered by this Policy must also comply with the current Regulation on Conflicts of Interest for CRCHUM executives, staff, and professionals. In case where there is a contradiction between the Regulation and this Policy, the Regulation will take precedence.

4 CONFLICT OF INTEREST

- 4.1** Individuals concerned to this Policy must always avoid placing themselves in a real, potential or apparent conflict of interest in where they might have to choose between their personal interests (financial, career-related or other), including those of their Relatives, and the interests of the CRCHUM or the Institution.

- 4.2** Depending on circumstances, individuals must abstain from attending or participating in any deliberation or decision involving a company in which they hold an interest, or any situations listed in paragraph 5.1.
- 4.3** Individuals must, depending on the case, take immediate measures to prevent any situation of conflict of interest listed in paragraph 5.1.

5 SITUATIONS OF CONFLICT OF INTEREST

- 5.1** Without limiting the general application of this Policy, a conflict of interest in the context of research activities arises in the following circumstances.
 - 5.1.1** Individual has, directly or through his/her Relatives, a financial or other interest in an external company that conducts or is likely to conduct business with the CRCHUM or the Institution.
 - 5.1.2** When an individual concludes a contract with an external company in which they or their Relatives hold financial or other interests.
 - 5.1.3** When an individual directs their research activities at the CRCHUM to benefit the needs of an external company in which they or their Relatives have financial or other interest.
 - 5.1.4** When an individual, as a committee member uses their influence or voting rights to promote their own projects or those of their Relatives, or others.
 - 5.1.5** When an individual conducts research activity on behalf of an external company without regard to the rights of the CRCHUM or the Institution.
 - 5.1.6** When an individual engages in professional or other activities that, due to the time they required, compromise their accomplishment of research activities or duties at the CRCHUM.
 - 5.1.7** When an individual accepts a gift, hospitality or other benefit from an external company conducting business with the CRCHUM or the Institution. Any other gift, hospitality or benefit received must be returned to the donor or transferred to the CRCHUM or the Institution.
 - 5.1.8** When an individual use grant, solicits or accepts a favor or advantage for itself or a third party, including Relative, in exchange for a position, an intervention or a service.
 - 5.1.9** Resources: When an individual use by the authority of their position, resources, goods, services, or allocated time of the CRCHUM or the Institution for personal purposes or for the benefit of a third-party including Relatives.
 - 5.1.10** When an individual using the name, symbols, logo of the CRCHUM or the Institution for personal purposes.

5.1.11 When an individual participating in the recruitment or promotion, within the CRCHUM or the Institution, of a family member, a Relative, or other persons with whom they are associated.

5.1.12 When an individual uses any confidential information acquired during their research activities or duties at the CRCHUM or the Institution for personal purposes or for the benefit of a third party.

5.2 Individual who has ceased research activities or duties with the CRCHUM must in manner that prevent from deriving undue benefit from their previous roles or to harm the interests of the CRCHUM or the Institution.

5.3 When individual who has stop research activities or duties with the CRCHUM must refrain from disclosing any confidential or privileged information obtained during their research activities or duties with the CRCHUM and the Institution.

5.4 When an individual chooses to participate in activities with a private company, they must obtain prior authorization from the CRCHUM and establish an agreement on the terms and conditions for continuing their roles as a researcher, student or employee.

6 DECLARATION OF INTEREST

Any situation in which individuals might have to choose between their personal interests, including those of their Relatives, of a financial or other nature, and those of the CRCHUM or the Institution must be disclosed in accordance with Procedure 50 401 A provided for this purpose. In the absence of such situations, individuals are required to complete, sign and submit the annual declaration form.

7 CONFLICT OF INTEREST IN THE CONTEXT OF GRANTS AWARDED BY AMERICAN PUBLIC HEALTH ORGANIZATIONS

The U.S. Public Health Services (PHS) of the U.S. Department of Health and Human Services (DHHS), which includes the National Institutes of Health (NIH), has adopted on 26 September 2011 a federal policy that establishes guidelines for the disclosure of financial interests to promote objectivity in research. This new policy has been in force since 24 August 2012. The CRCHUM is required to comply with U.S. federal regulations on financial conflicts of interest relating to research activities when research is carried out at the CRCHUM and funded by a U.S. public health agency, whether through a grant or a collaborative agreement.

The term "research" includes any activity that receives funding from a U.S. public health agency, either directly or through a transfer of funds from another institution. Examples include, research projects, career development grants, center grants, individual awards, infrastructure grants, and other similar initiatives.

7.1 Individual concerned

Individuals covered by section 7 of the Policy are those, regardless of their title or position, who are responsible for designing a research project, have obtained funding or intend to submit applications, directly or indirectly, to the NIH or other U.S. agencies subject to DHHS rules.

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In addition to carrying out their usual responsibilities in accordance with law, Institution's regulations, and policies, individuals must be familiar with this Policy, complete the mandatory training, declare any SFI of themselves or their Relatives, and comply to the management plan established by the CRCHUM in the event of an SFI.

7.2 Funding organizations concerned

The funding organizations concerned by section 7 of the Policy are American public health organizations and certain American foundations that, while not governed by the PHS, have chosen to adopt the same policies. These organizations include, but are not limited to:

- ▶ Administration for Children and Families
- ▶ Administration on Aging Agency for Healthcare Research and Quality (AHRQ)
- ▶ Agency for Toxic Substances and Disease Registry (ATSDR)
- ▶ American Asthma Foundation
- ▶ American Cancer Society (ACS)
- ▶ Alliance for Lupus Research (ALR)
- ▶ American Heart Association (AHA)
- ▶ American Lung Association (ALA)
- ▶ Arthritis Foundation (AF)
- ▶ Centres pour le contrôle et la prévention des maladies (CDC)
- ▶ Federal Occupational Health
- ▶ Food and Drug Administration (FDA)
- ▶ Health Resources and Services Administration (HRSA)
- ▶ Indian Health Service (IHS)
- ▶ Juvenile Diabetes Research Foundation (JDRF)
- ▶ Lupus Foundation of America (LFA)
- ▶ National Institutes of Health (NIH)
- ▶ Substance Abuse and Mental Health Services Administration (SAMHSA)
- ▶ Susan G. Komen for the Cure
- ▶ CurePSP

7.3 Significant financial interest (SFI)

7.3.1 Definition: An SFI arises when one or more of the interests listed below could reasonably be linked to the institutional responsibilities of the individual concerned:

1. any remuneration received by the individual or their Relatives from an institution other than the Institution in the last twelve (12) months, with a cumulative value of \$5,000 USD or more. This includes: salaries, payment for services rendered (consulting fees, honoraria, and other), and shareholding or interest in a company or other organization (e.g., shares, stock options).
2. income and financial interest from intellectual property rights.
3. paid travel or reimbursed travel expenses starting from the first dollar.

7.3.2 The following situations are not considered SFIs under this Policy:

1. Salaries and additional remuneration paid to an individual from fund administered by the Institution, salary support for researchers or copyright royalties paid by the Institution.
2. Intellectual property rights assigned to the Institution and royalty-sharing agreements related to these rights.
3. Income from investment funds, mutual funds, or pension funds, provided the individual does not control the fund(s).
4. Income from seminars, teaching, or travel reimbursements paid by: U.S. government agency, U.S. institution of higher education, U.S. teaching hospital, a research center or institute affiliated with a U.S. institution of higher education.
5. Income received for participation in advisory or review committees for: U.S. government agency, U.S. institution of higher education, U.S. teaching hospital or, research center or institute affiliated with a U.S. institution of higher education.

7.4 Financial Conflicts of Interest (FCOI)

The FCOI arises when an SFI could, directly or indirectly, influence the design, execution or reporting of a research project funded by one of the granting agencies.

7.5 Declaration of Significant Financial Interest (SFI)

Individuals must disclose their own SFI, or those from their Relatives in the following instances: at the time of submitting a grant application, within thirty (30) days of the appearance of a new SFI, and annually.

SFI declarations must follow the procedure outlined in Procedure 50 401 A.

7.6 Transfer of grants and/or participation in research activities

When individuals from another institution or company collaborate on research activity, or entrusted with partial or complete execution, the principal investigator must obtain a written declaration from this institution or company. In the event where all or part of the grant awarded to the CRCHUM is transferred to another institution, the obligations outlined in this section (7) concerning the declaration of SFI and FCOI must be imposed on the receiving institution.

A written agreement is signed between the Institution and the receiving institution, which the other institution:

1. The receiving institution declares that its conflicts of interest policy comply with U.S. federal regulations on financial conflicts of interest in research, or undertakes to comply with this Policy.
2. The receiving institution declares undertakes to forward to the Institution declarations of SFI and FCOI, enabling the Institution to submit timely reports to the relevant granting agency in accordance with the deadlines established by this Policy.

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3. The receiving institution declares that they have completed a training on financial conflicts of interest prior to initiating a research project and commits to renewing this training every four (4) years or as requested and agrees to complete immediately in the cases listed in section 7.7.

7.7 Mandatory training

Individuals concerned by section 7 of the Policy must complete training on financial conflicts of interest prior to initiating any research project funded by the granting agencies concerned. This training must be renewed every four (4) years, upon request by the CRCHUM, or immediately under the following cases:

1. Significant change to this Policy.
2. Appointment of the individual as a new researcher at the CRCHUM.
3. Identification of the individual as non-compliant with this Policy or with the management plan established by the committee.

7.8 Authorization for transmission of SFI and FCOI

By signing the SFI and FCOI, the individual authorizes the Institution to share the information with the relevant Granting Agency.

8 RESPONSIBILITY FOR POLICY ENFORCEMENT

The CRCHUM Director is responsible for implementation and enforcement of the Policy and Procedure. The Director provides annual reports to the CRCHUM Board of Directors and, if necessary, proposes amendments to the Policy and Procedure.

9 SANCTION

Any individual who contravenes this Policy is subject to sanctions in accordance with the applicable regulatory framework.

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10 APPLICATION

This Policy becomes effective on the day of its approval by the Research Director of the CHUM.

_Signed on the original French version _____

Vincent Poitout, DVM, PhD, FCAHS

Research Director, CHUM and Scientific Director, CRCHUM

Centre hospitalier de l'Université de Montréal
Direction de la recherche
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