

1.0 Purpose

This supplemental policy is made under the CAMH policy *AL 1.2 – Relationship Attestation and Disclosure*. CAMH is dedicated to ensuring that there is no reasonable expectation that the design, conduct or reporting of research conducted under its auspices or in affiliation/association with CAMH is biased or appears to be biased by research personnel conflict of interest (COI).

The United States Department of Health and Human Services released two sets of Financial Conflict of Interest Regulations for the Public Health Service (PHS), both effective August 24, 2012 (collectively, the “**Regulations**”):

- Promoting Objectivity in Research – [42 C.F.R Part 50, Subpart F](#)
 - Applies to institutions that apply for, or receive, PHS research funding by means of grants or cooperative agreements, and to each Investigator that participates in such research.
- Responsible Prospective Contractors – [45 C.F.R. Part 94](#)
 - Applies to institutions that submit a proposal for, or receive, PHS research funding by means of a contract for property or services for the direct benefit or use of the U.S. federal government, and to each Investigator that participates in such research.

The purpose of the Regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements or research performed under PHS contracts will be free from bias resulting from Investigator financial conflicts of interest (FCOI).

The purpose of this supplemental policy is to implement the requirements of the Regulations with respect to PHS-Funded Research conducted at or under the auspices of CAMH. One of the requirements of the Regulations is that institutions maintain an up-to-date, written, enforced policy on FCOI that complies with the Regulations. This supplemental Policy is intended to fulfill that requirement.

2.0 Persons Affected

This supplemental policy applies to all Investigators participating, or planning to participate, in PHS-Funded Research conducted at or under the auspices of CAMH. Any Research Personnel who chooses to apply for or accept PHS research funding or to work on PHS-Funded Research and who meets the definition of Investigator below must comply with this supplemental policy and the Regulations which this supplemental policy implements.

The Regulations apply to all institutions, both U.S. or foreign, applying for or receiving PHS research funding, including funding that is received as a sub-award from another institution. This supplemental policy also sets out the obligations of CAMH with respect to Investigator FCOI where research is funded by the PHS.

3.0 Policy

FCOI (actual, perceived or potential) will be identified, disclosed, appropriately considered and managed or mitigated in compliance with the requirements of the Regulations for all research funded or proposed to be funded by the PHS.

4.0 Definitions

Designated Official: the institutional official(s) designated to solicit and review disclosures of Significant Financial Interests (SFI) from all Investigators, determine whether a FCOI exists, and approve management plans to manage any FCOI. At CAMH, the Designated Official is the Research Integrity Officer and their delegate(s).

Financial Conflict of Interest or FCOI: a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct or reporting of PHS-Funded Research.

Financial Interest: anything of monetary value, whether or not the value is readily ascertainable.

HHS: the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institutional Responsibilities: an Investigator's professional responsibilities on behalf of CAMH, and, if applicable, as defined by CAMH in its policy on FCOI, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards/Research Ethics Boards or Data and Safety Monitoring Boards.

Investigator: the principal investigator or project lead, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of PHS-Funded Research or research proposed for such funding, which may include, for example, CAMH Research Personnel, collaborators or consultants.

PHS: the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component: the organizational unit of the PHS that funds the research that is subject to the Regulations.

PHS-Funded Research: research funded by the PHS.

Research Personnel: all CAMH employees (including but not limited to research coordinators, research analysts, research assistants, research associates, research methods specialists), as well as researchers/investigators, principal investigators, qualified investigators, scientific appointees, clinicians, contractors, physicians, trainees, volunteers, and affiliates who are involved in research conducted at or under the auspices of CAMH.

Significant Financial Interest or SFI:

(1) A Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse/common law partner and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

- i. With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the 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. 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;

- ii. With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse/common law partner or dependent children) holds any equity interest (e.g. stock, stock option, or other ownership interest); or
- iii. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

(2) Any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to an Investigator's Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

(3) The term SFI does not include the following types of financial interests:

- salary, royalties, or other remuneration paid by CAMH to the Investigator if the Investigator is currently employed or otherwise appointed by CAMH, including intellectual property rights assigned to CAMH and agreements to share in royalties related to such rights;
- 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;
- income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
- income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

5.0 Responsibilities

5.1 Investigator

- Review CAMH's conflict of interest/relationship management policies, and complete training on the Investigator's responsibilities regarding disclosure of SFIs and the Regulations via the [NIH Financial Conflict of Interest online tutorial](#);
- Disclose SFIs of the Investigator (and those of the Investigator's spouse/common law partner and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities (see *AR 1.9.2 – Research Conflict of Interest*);
- Assist with the development of a management plan of any identified FCOIs;
- Comply with this supplemental policy and with any management plan developed to manage any identified FCOIs;
- Assist with completing any reports that are required to be provided to the PHS; and
- Comply with any other obligations under the Regulations.

5.2 CAMH

- Designating a Designated Official to solicit and review disclosures of SFIs and determine if a FCOI exists;
- Providing guidelines for the Designated Official for determining whether an Investigator's SFI is related to the PHS-Funded Research and, if so, whether it is a FCOI;
- Managing FCOIs, including through the development and implementation of management plans;
- Providing FCOI reports to the PHS Awarding Component; and
- Complying with any other obligations under the Regulations.

6.0 Procedure

6.1 Training

Each Investigator must make themselves familiar with this supplemental policy (including the responsibilities regarding disclosure of SFIs) and the Regulations, and must complete the NIH on-line interactive tutorial (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html):

- prior to engaging in PHS-Funded Research;
- at least once every 4 years; and
- immediately when any of the following circumstances apply:
 - CAMH revises this supplemental policy or procedures relating to FCOI policies in any manner that affects the requirements of Investigators;
 - An Investigator is new to CAMH, even if the PHS-Funded Research has already begun; or
 - An Investigator is not in compliance with this supplemental policy or a management plan, as determined by the Designated Official.

When the NIH on-line tutorial has been completed, the Investigator must save an electronic copy of the certificate generated through the system and upload it to RTED (Centralized Repository of Research Training and Education Documents).

Each Investigator will be required to complete any other training mandated by NIH, as applicable.

6.2 Disclosure of SFIs

6.2.1 **What to disclose**

Each Investigator who is planning to participate in or who is participating in PHS-Funded Research (e.g. any Investigator applying for or receiving PHS funds whether directly or indirectly through a subcontract) must disclose all of their SFIs (and those of the Investigator's spouse/common law partner and dependent children). Disclosure of any reimbursed or sponsored travel must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration and the monetary value. The Designated Official may require further information in order to determine whether the travel constitutes a FCOI with the PHS-Funded Research. Any annual updates shall include any information that was not disclosed previously (e.g. in the initial disclosure or in a subsequent disclosure of SFIs) or updated information regarding any previously disclosed SFI (e.g. the updated value of a previously disclosed equity interest).

The principal investigator is responsible for ensuring that all Investigators involved in the principal investigator's PHS-Funded Research are aware of and make any disclosures required under this supplemental policy.

6.2.2 When to disclose

Disclosure must be made:

- No later than at the time of application or date of submission of proposal for PHS-Funded Research (or, in the case of a sub-award, no later than at the time of application for funding from the prime institution);
- At least annually during the period of the PHS award;
- Within 30 days of discovering or acquiring (e.g. through purchase, marriage or inheritance) a new SFI; and
- When a new Investigator joins an ongoing project.

6.2.3 How to disclose

Each Investigator must complete the Conflict of Interest Disclosure Form within CAMH's eRA system. If an Investigator is not sure whether a particular Financial Interest is significant and should be disclosed, the Investigator should disclose it or contact Research.COI@camh.ca.

6.3 Review of SFIs and Determination of FCOIs

6.3.1 The Designated Official will review disclosures of SFIs from each Investigator who is planning to participate in, or is participating in, PHS-Funded Research, together with any other information deemed relevant.

6.3.2 The Designated Official will determine if an Investigator's SFI is related to PHS-Funded Research and, if it is, determine whether the SFI is a FCOI.

- An Investigator's SFI is related to PHS-Funded Research when it is reasonably determined that the SFI could be affected by the PHS-Funded Research or is in an entity whose Financial Interest could be affected by the PHS-Funded Research. CAMH may involve the Investigator in the determination of whether a SFI is related to the PHS-Funded Research.
- A FCOI exists when it is reasonably determined that the SFI could directly and significantly affect the design, conduct or reporting of PHS-Funded Research.

6.3.3 The Designated Official may consult with the VP Research (or delegate), the CAMH Research Ethics Board or the CAMH Relationship Management Committee and may request further information from the Investigator.

6.3.4 CAMH is responsible for reviewing and making the determinations described above in section 6.3 and taking such actions required to manage any FCOIs as described below in section 6.4 prior to CAMH's expenditure of any funds under a PHS-funded research project.

6.4 Management of FCOIs

Where a FCOI exists, CAMH may take such actions as necessary to manage the FCOI (including any FCOI of a subrecipient Investigator), including the development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report (see section 6.6 below).

6.4.1 Management Plans

Prior to the expenditure of any funds under a PHS-funded research project, if the Designated Official determines that a FCOI exists, a management plan will be developed and implemented in consultation as appropriate with the Investigator determined to have the FCOI. Each management plan shall specify the actions that have been, and shall be, taken to manage the FCOI and a mechanism for monitoring compliance with the management plan until the completion of the PHS-funded research project (see CAMH policy *AL 1.2 – Relationship Attestation and Disclosure* for further information on management plans).

Examples of conditions or restrictions that might be imposed to manage a FCOI for PHS-Funded Research include, but are not limited to:

- Public disclosure of the FCOI (e.g. when presenting or publishing the research);
- For PHS-funded research projects involving human subjects research, disclosure of the FCOI directly to the participants, as approved by the Research Ethics Board;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the PHS-Funded Research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the PHS-Funded Research;
- Reduction or elimination of a financial interest (e.g. sale of an equity interest); or
- Severance of relationships that create the FCOI.

6.5 New SFIs disclosed during ongoing PHS-Funded Research

Whenever, in the course of ongoing PHS-Funded Research: an Investigator who is new to participating in the PHS-Funded Research discloses a SFI, an existing Investigator discloses a new SFI or CAMH identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by CAMH (e.g. was not reported by a subrecipient), the Designated Official will, within 60 days:

- review the disclosure of the SFI;
- determine whether it is related to PHS-Funded Research;
- determine whether a FCOI exists, and, if so;
- implement, at least on an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI.

Depending on the nature of the SFI, the Designated Official may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-Funded Research project between the date of disclosure and the completion of the Designated Official's review.

6.6 Retrospective Review and Mitigation Report

- **Retrospective Review:** Whenever a FCOI is not identified or managed in a timely manner, including:

- a) failure by the Investigator to disclose a SFI that is determined by CAMH to constitute a FCOI;
 - b) failure by CAMH to review or manage such a FCOI; or
 - c) failure by the Investigator to comply with a FCOI management plan,
- the Designated Official will, within 120 days of CAMH's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-Funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The Designated Official will document the retrospective review in accordance with the Regulations (including such key elements as set out in the Regulations), and based on the results of the retrospective review, if appropriate, will update the FCOI report previously submitted to the PHS Awarding Component, specifying the actions that will be taken to manage the FCOI going forward.

- **Notification and Mitigation Report:** If the Designated Official finds bias in the design, conduct, or reporting of PHS-Funded Research based on the results of the retrospective review, the Research Integrity Office will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and CAMH's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g. impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, CAMH will submit FCOI reports annually as specified in the Regulations (see section 6.7 below).
- **Interim Measures.** Depending on the nature of the FCOI, the Designated Official may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-Funded Research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of the retrospective review.

6.7 Reporting and notification requirements to PHS of FCOIs

CAMH will send reports to the PHS Awarding Component at the following times:

- Prior to the expenditure of any PHS funds
 - Prior to CAMH's expenditure of any funds under PHS-Funded Research, the Designated Official shall provide to the PHS Awarding Component a FCOI report regarding any Investigator's FCOI and ensure that a management plan has been implemented. In cases in which a FCOI is identified and eliminated prior to the expenditure of PHS-awarded funds, CAMH shall not submit a FCOI report to the PHS Awarding Component.
- Subsequent to the initial FCOI report, during an ongoing project:
 - For any SFI that CAMH identifies as conflicting subsequent to the initial FCOI report during an ongoing PHS-Funded Research Project (e.g. upon the participation of an Investigator who is new to the research project), CAMH shall provide to the PHS

Awarding Component, within 60 days, a FCOI report regarding the FCOI and ensure that it has implemented a management plan.

- For any FCOI previously reported by CAMH with regard to an ongoing PHS-funded research project, the Designated Official shall provide the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-Funded Research. The annual FCOI report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. CAMH shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.
- For FCOIs not previously disclosed, reviewed or managed during ongoing PHS-Funded Research requiring a retrospective review pursuant to section 6.5 above, the Designated Official shall, if the retrospective review results in a finding of bias in the design, conduct or reporting of the PHS-Funded Research, notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

Any FCOI report required under the Regulations shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI, and to assess the appropriateness of CAMH's management plan and will contain all the information required under the Regulations.

The Designated Official on behalf of CAMH shall, upon request of the HHS, make information available to the HHS relating to any Investigator disclosure of financial interests and CAMH's review of, and response to, such disclosure, whether or not the disclosure resulted in CAMH's determination of a FCOI.

If the CAMH policy on FCOIs includes standards that are more stringent than the Regulations (e.g. it requires a more extensive disclosure of financial interests), CAMH shall adhere to its policy and provide FCOI reports regarding identified FCOIs to the PHS Awarding Component in accordance with CAMH's own standards and within the timeframe prescribed by the Regulations.

6.8 Public Accessibility

6.8.1 This supplemental policy is made publically available on CAMH's website.

6.8.2 Upon written request from a member of the public addressed to the Designated Official, the Designated Official will, within 5 business days of the request, provide information to the requestor concerning any SFI disclosed to CAMH that meets the following criteria:

- a. The SFI was disclosed and is still held by the senior/key personnel. Senior/key personnel means: (i) in the case of a PHS grant, the principal investigator or project director of the PHS-funded research project and any other person identified as senior/key personnel by CAMH in the grant application, progress report, or any other report submitted to the PHS by CAMH under the Regulations; or (ii) in the case of a PHS contract, the principal investigator or project director of a PHS-funded research project and any other personnel considered to be essential to work performance in accordance with HHSAR subpart 352.237-75 and identified as key personnel in the contract proposal and contract;

- b. CAMH has determined that the SFI is related to the PHS-Funded Research; and
 - c. CAMH has determined that the SFI is a FCOI.
- 6.8.3 CAMH will include in its written response to the requestor, at a minimum, the following:
- a. the Investigator's name, title and role with respect to the research project;
 - b. the name of the entity in which the SFI is held;
 - c. the nature of the SFI;
 - d. the approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$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
 - e. a statement that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of CAMH's identification of a new FCOI, which should be requested subsequently by the requestor.
- 6.8.4 Information concerning the SFIs of senior/key personnel subject to section 6.8.2 shall remain available, for responses to written requests for at least 3 years from the date that the information was most recently updated.

6.9 Requirements regarding Subrecipients

- 6.9.1 If CAMH carries out the PHS-Funded Research through a subrecipient (e.g. subcontractors or consortium members), CAMH will take reasonable steps to ensure that any subrecipient Investigators comply with the Regulations by establishing, as part of a written agreement with the subrecipient, whether the FCOI policy of CAMH or that of the subrecipient will apply to the subrecipient's Investigator(s).
- 6.9.2 If the subrecipient's FCOI policy applies:
- a. the subrecipient must certify in the subrecipient written agreement that its policy complies with the Regulations, and that the subrecipient's Investigators will comply with the subrecipient's policy (if the subrecipient cannot provide such certification, the subrecipient written agreement shall state that subrecipient Investigators are subject to the FCOI policy of CAMH for disclosing SFIs that are directly related to the subrecipient's work for CAMH); and
 - b. the subrecipient written agreement will specify the time period(s) for the subrecipient to report all identified FCOIs of its Investigators to CAMH. Such time period(s) will be sufficient to enable CAMH to provide timely FCOI reports, as necessary, to the PHS as required under the Regulations.
- 6.9.3 If CAMH's FCOI policy applies:
- a. the subrecipient written agreement shall state that subrecipient Investigators are subject to CAMH's FCOI policy for disclosing all SFIs that are directly related to the subrecipient's work for CAMH;

- b. the subrecipient written agreement will specify time period(s) for the subrecipient to submit all Investigator disclosure of SFIs to CAMH. Such time period(s) shall be sufficient to enable CAMH enough time to comply with its review, management and reporting obligation under the Regulations.

6.9.4 CAMH will be responsible for providing FCOI reports to the PHS Awarding Component regarding all FCOIs of all subrecipient Investigators, i.e. prior to expenditure of funds and within 60 days of any subsequently identified FCOI.

6.10 Compliance and Remedies

6.10.1 Investigators must comply with this supplemental policy and with any management plan developed to manage a FCOI.

6.10.2 Noncompliance with this supplemental policy, including failure to disclose SFIs or failure to comply with any management plan, may constitute research misconduct under the policy *AR 1.9.1 – Research Misconduct*. In the event of noncompliance with any requirements under this supplemental policy (e.g. including, but not limited to, failure to complete required training or to submit a Conflict of Interest Declaration Form), access to PHS funds or eligibility to engage in research may be suspended and CAMH may take corrective or remedial actions in accordance with applicable CAMH policies and procedures. Such actions may require giving notice to professional bodies or journals, or the public.

6.10.3 The Regulations set out the following powers of the PHS Awarding Component and the HHS:

- a. If the failure of an Investigator to comply with this supplemental policy or a management plan appears to have biased the design, conduct, or reporting of PHS-Funded Research, CAMH shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to CAMH for further action, which may include directions to CAMH on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, require institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator or impose such other remedies as set out in the Regulations.
- b. The PHS Awarding Component and/or HHS may inquire at any time before, during, or after the award into any Investigator disclosure of financial interests and CAMH's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in CAMH's determination of a FCOI. CAMH is required to submit, or permit on site review of, all records pertinent to compliance with the Regulations. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS-Funded Research to such an extent that further corrective action is needed or that CAMH has not managed the FCOI in accordance with the Regulations. The PHS Awarding Component may determine that imposition of specific award conditions or suspension of funding or other enforcement action is necessary until the matter is resolved.

- c. In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by CAMH as required by the Regulations, the Investigator involved will be required to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

6.11 Maintenance of Records

CAMH will maintain records relating to all Investigator disclosures of financial interests and CAMH's review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of a FCOI), and any other action under this supplemental policy or retrospective review, if applicable, for a minimum period of: (i) in the case of a PHS grant, 3 years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 75.361 for different situations; or (ii) in the case of a PHS contract, 3 years from the date of final payment or, where applicable, for the time periods specified in 48 CFR part 4, subpart 4.7.